NRC Staff Response to Fukushima Near-Term Task Force Recommendation1

NOTE: *Public availability of this draft document is intended to inform stakeholders of the current status of the NRC staff's evaluation of possible activities in response to Fukushima Near-Term Task Force (NTTF) Recommendation 1. The NRC staff believes that making this information public about a week before an NRC public meeting on November 8, 2012, will allow stakeholders to review the material in advance and facilitate more constructive and informed discussion during the meeting. The NRC staff will review and consider any comments received for information only and will not respond to any comments received at this meeting nor provide detailed written responses to comments. Comments may be submitted via www.regulations.gov. Search for Docket NRC-2012-0173. Comments must be submitted by December 7, 2012. This unapproved draft may be incomplete or in error in one or more respects and will be subject to further revision before the staff presents its recommendations for dispositioning NTTF Recommendation 1 to the Commission in a SECY paper (currently scheduled to be provided to the Commission in early February 2013).*

BACKGROUND:

Following the accident at the Fukushima Dai-ichi nuclear power plant in March of 2011, the Commission established an NTTF of senior NRC managers to conduct a systematic and methodical review of NRC processes and regulations to determine whether the agency should make additional improvements to its regulatory system. The NTTF was also tasked to make recommendations to the Commission for its policy direction on this question (Tasking Memorandum COMGBJ-11-0002 (March 23, 2011) and SRM-COMGBJ-11-0002 (ADAMS Accession Nos. ML110800456 and ML 110820875, respectively)). The NTTF issued its Report on July 12, 2011 (ADAMS Accession No. ML111861807), as an enclosure to SECY-11-0093 (ADAMS Accession No. ML11186A959).

The NTTF developed 12 overarching recommendations. Recommendation 1 stated that the NRC should establish a "*logical, systematic, and coherent regulatory framework for adequate protection that appropriately balances defense-in-depth and risk considerations."* (NTTF Report, p.22.). In the August 19, 2011, SRM for SECY-11-0093 (ADAMS Accession No. ML112310021), the Commission set forth its directions to the staff with respect to the recommendations in the NTTF Report. On Recommendation 1, the Commission directed:

> *Recommendation 1 should be pursued independent of any activities associated with the review of the other Task Force recommendations. Therefore, the staff should provide the Commission with a separate notation vote paper within 18 months of the issuance of this SRM. This notation vote paper should provide options and a staff recommendation to disposition this Task Force recommendation.*

Also, on June 14, 2012, Chairman Jaczko issued a tasking memorandum (ADAMS Accession No. ML121660102) directing the NRC staff to consider the regulatory framework recommendations for power reactors in Commissioner Apostolakis' Risk Management Task Force (RMTF) report (NUREG-2150; April 2012; ADAMS Accession No. ML12109A277) in developing options for Recommendation 1.

This unapproved draft document contains detailed descriptions of the options that the NRC staff working group (WG) is currently evaluating. It presents the staff's estimates of NRC and licensee resources needed to implement the options and suggests various pros and cons associated with each.

The options are listed below:

Option 1 – Maintain the existing regulatory framework (status quo)

Option 2 – Clarify the role of voluntary industry initiatives in the NRC's regulatory process

Option 3 – Establish process and considerations for balancing risk, defense-in-depth and safety margins in NRC decisionmaking

Option 4 – Develop and implement a design-basis enhancement category for regulatory requirements related to beyond design-basis events and severe accidents (this category could be established in two different ways)

Option 4a – Establish a design-basis extension category on a generic basis (similar to Alternative 1 of Appendix H to NUREG-2150)

Option 4b – Require licensees to perform a plant-specific PRA to establish and maintain a plant-specific design basis enhancement category (similar to Alternative 2 of Appendix H to NUREG-2150)

These options are described in detail on the following pages.

Estimated industry and NRC implementation costs for each option are included in the Appendix.

Option 1: Maintain Existing Regulatory Framework (Status Quo)

Summary of Option

Option 1 constitutes a decision not to adopt Recommendation 1. The NTTF report referred to a portion of the NRC's existing regulatory framework as a "patchwork," but also concluded that the framework overall has served the NRC well in providing reasonable assurance of adequate protection of public health and safety. Under Option 1, there would be no structural changes to existing NRC policies or processes. Emergent issues with potential safety impact would continue to be handled as they currently are, as is the case for the actions now underway as a result of the Fukushima accident. The NRC's approach to the defense-in-depth philosophy would be to retain it as a general philosophy, there would be no new category of events or accidents (e.g., for extended or enhanced design basis events). The Commission would provide no new direction regarding the role of voluntary industry initiatives in the NRC's regulatory processes for addressing emergent safety issues not related to adequate protection. Probabilistic Risk Assessment studies would not become a requirement for currently operating reactors. Periodic safety reassessments would not be required.

Selection of Option 1, however, would not mean that the NRC would *never* make changes to improve its regulatory processes. Under Option 1 the Commission would continue, on appropriate occasions, decide to improve various aspects of its regulatory processes. This is exemplified by the NRC actions taken, and which will be taken.

Following the Fukushima accident, in the 19-month period to date, the NRC has effectively utilized its current regulatory framework to perform inspections, issue orders, and undertake rulemaking that already have resulted in, and will in the future provide significant safety enhancements to U.S. nuclear power reactor facilities.

Pros and Cons for this Option

<u>Pros</u>:

- The NRC's current regulatory framework has served well and provides reasonable assurance of adequate protection; there is no substantial safety reason for changing the framework.
- The current framework has proved sufficient to address new issues as they arise, including the major regulatory actions taken after the TMI-2 and Fukushima Dai'ichi events.
- The current framework allows for improvements in efficiency and efficacy as they are identified. For example, the question regarding how to address voluntary industry initiatives in the future (included as part of Option 2) could be addressed under the current framework through a staff-initiated Commission paper and subsequent policy statement.
- There are no necessary additional resource expenditures for NRC or licensees associated with maintaining the existing framework relative to the current level. Any improvement actions would be identified and justified on their own merits, as currently is the practice.

Cons:

- Several of the improvement activities identified by the WG require Commission policy decisions. If the Commission desires that certain improvements noted in these options should be implemented, it would be more efficient to undertake these activities in an integrated fashion than to address those activities separately under the existing regulatory framework.
- The current NRC processes for evaluating new information and taking appropriate action could be more timely. For example, Generic Issues, on average, take about eight years to resolve. Maintaining the status quo would not provide as great an impetus for improving these processes compared to adopting Options 2, 3 and 4.
- This option does not address NTTF Recommendation 1; that is, this option concludes that the NTTF's recommendation does not need to be implemented. There could be adverse reaction from some interested parties and groups should the NRC decide not to take action to implement Recommendation 1.

Estimated Resources

There are no industry or NRC costs or resource impacts associated with this option.

Option 2 – Clarify the role of voluntary industry initiatives in the NRC's regulatory process

Summary of Option

This option would clarify the role of voluntary industry initiatives in NRC's regulatory processes by defining when or under what circumstances the NRC would incorporate such initiatives into regulatory requirements (e.g., rules, orders, license conditions). It is well established that the NRC staff does not rely on voluntary industry initiatives in lieu of regulatory action to resolve matters related to providing reasonable assurance of adequate protection. However, the proper role of such initiatives in other regulatory areas is not always as clear. This option would either (1) provide clear expectations and criteria for when certain voluntary initiatives should be subject to a legally binding requirement, or (2) address the proper handling of voluntary industry initiatives and other matters as part of an integrated approach involving clarification of defense in depth (Option 3) and beyond-design-basis events (Option 4).

Background

The NRC has a long history of encouraging licensees and the nuclear industry as a whole to take the initiative to address safety or other issues related to nuclear plant designs and operation. NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," describes industry initiatives as follows:

> Industry initiatives can generally be put into one of the following categories—
>
> (1) those put in place in lieu of, or to complement, a regulatory action to ensure that existing requirements are met,
>
> (2) those used in lieu of, or to complement, a regulatory action in which a substantial increase in overall protection could be achieved with costs of implementation justifying the increased protection, and
>
> (3) those that were initiated to address an issue of concern to the industry but that may or may not be of regulatory concern.
>
> Issues related to adequate protection of public health and safety are deemed the responsibility of the NRC and should not be addressed through industry initiatives.

The NRC has on several previous occasions considered policy issues related to voluntary commitments or initiatives. The decision to develop guidelines for using industry initiatives in the regulatory process was an outgrowth of the Commission's Direction Setting Initiative (DSI) 13, which was published as part of SECY-97-303, "The Role of Industry (DSI-13) and Use of Industry Initiatives," dated December 31, 1997 (ADAMS Accession No. ML992950105), and the associated April 16, 1998, staff requirements memorandum (SRM) (ADAMS Accession No. ML003753845). The staff proposed in SECY-99-063, "The Use by Industry of Voluntary Initiatives in the Regulatory Process," on March 2, 1999 (ADAMS Accession No. ML992810068), the development of NRC guidelines for crediting industry initiatives in lieu of taking regulatory action. On May 27, 1999, the Commission issued an SRM (ADAMS Accession No. ML003752062) approving the staff's recommendations in SECY-99-063. In this SRM, the Commission agreed that the current regulatory framework does not preclude voluntary industry initiatives and that existing regulatory processes can be used to support implementation of voluntary initiatives as long as such initiatives will not be used in lieu of regulatory action where a question of adequate protection exists. The SRM directed the staff to work with the industry and other stakeholders in developing the guidelines for using industry initiatives. These guidelines were developed and provided to the Commission in SECY-00-0116, "Industry Initiatives in the Regulatory Process," on May 30, 2000 (ADAMS Accession No. ML003718488). In response to the June 28, 2000, SRM on SECY-00-0116 (ADAMS Accession No. ML003727346), the staff revised the proposed guidelines as directed by the Commission and published them for public comment on August 31, 2000 (65 FR 53050).

After reviewing public comments, the staff found that stakeholders perceived the proposed guidelines on industry initiatives as imposing a burdensome obstacle to open and candid interactions. In view of the stakeholders' reluctance to embrace the proposed guidelines, the staff concluded that implementing this largely voluntary process would be ineffective. Thus, in SECY-01-0121, "Industry Initiatives In the Regulatory Process," on July 5, 2001 (ADAMS Accession no, ML011630126), the staff requested Commission approval to notify all stakeholders that the proposal to implement a new industry initiative program and related guidelines would be withdrawn. The Commission approved, in an SRM on August 2, 2001, (ADAMS Accession no, ML012140398). The program was withdrawn by an August 20, 2012 notice in the *Federal Register* (66 FR 43597).

The Fukushima Dai'ichi event highlighted that some measures previously put in place as voluntary initiatives in the U.S. to deal with severe accidents (e.g., severe accident management guidelines (SAMGs) and hardened vents), could have played a significant role in preventing or mitigating the accident. However, NRC assessments performed after the Fukushima event reinforced that these specific examples were not subject to NRC inspection or enforcement activities. In addition, the implementation and maintenance of the industry initiatives did not, in some cases, provide the desired degree of confidence that equipment or procedures would have worked as the NRC had intended when an industry initiative was accepted in lieu of taking a regulatory action. As discussed below, both the NTTF and the RMTF expressed concerns that in some cases use of licensee voluntary initiatives has led to inefficiencies and potentially less robust resolutions of issues. The lack of inspection and enforcement for such initiatives, which has been NRC's practice, may have contributed to some measures implemented as part of voluntary initiatives to degrade over time.

Relationship to NTTF Recommendation 1

The NTTF stated that the current NRC regulatory approach includes the following:

- requirements for design-basis events with protection and mitigation features controlled through specific regulations or the general design criteria (Title 10 of the Code of Federal Regulations (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix A, "General Design Criteria for Nuclear Power Plants")

- requirements for some "beyond-design-basis" events through specific regulations (e.g., station blackout, large fires, and explosions)

- voluntary industry initiatives to address severe accident features, strategies, and guidelines for operating reactors"

The NTTF provided examples of voluntary industry initiatives:

- containment hardened vents for BWR Mark I designs
- some severe accident considerations (through the IPE and IPEEE programs)
- shutdown risk issues
- SAMGs
- Groundwater Protection Initiative

In several places in the NTTF report, the Task Force notes that voluntary initiatives have a place in NRC's regulatory framework, but notes that "... voluntary industry initiatives should not serve as a substitute for regulatory requirements but as a mechanism for facilitating and standardizing implementation of such requirements." The NTTF further notes that "... NRC inspection and licensing programs give ... little attention to industry voluntary initiatives since there are no requirements to inspect against."

The NTTF noted that voluntary industry initiatives had been valuable and useful in the past "… as a mechanism for facilitating and standardizing implementation of ... [NRC] requirements." The NTTF report cited the "... development of symptom-based emergency operating procedures (EOPs) in the 1980s and development of the EDMGs following the events of September 11, 2001 ... " as "... just two examples of notable industry contributions to effective implementation of regulatory initiatives."

However, the NTTF noted potential problems with some voluntary industry initiatives. Specifically those initiatives that were used to address safety concerns in lieu of the NRC developing and issuing regulatory requirements. To demonstrate this point, the NTTF requested that NRC inspectors collect information (TI 2515/184) on how each licensee had implemented SAMGs, a voluntary initiative. It also considered the results of an inspection (TI 2515/183) of required activities related to mitigation strategies codified in 10 CFR 50.54(hh). The NTTF wrote:

> Through these two inspection activities, the Task Force also had the opportunity to compare industry activities under a required program and a similar voluntary initiative (i.e., EDMGs and SAMGs). Both programs had been effectively implemented, including initial program formulation and licensee staff training. Those programs are now 10 to 20 years old, and some licensees have maintained both programs in a manner expected for an important safety activity, including in terms of maintenance, configuration control, training, and retraining. However, some licensees have treated the industry voluntary initiative (the SAMG program) in a significantly less rigorous and formal manner, so much so that the SAMG inspection would have resulted in multiple violations had it been associated with a required program. The results of the SAMG inspection do not indicate, nor does the Task Force conclude that, the SAMGs would not have been effective if needed. However, indications of programmatic weaknesses in the maintenance of the SAMGs are sufficient to recommend strengthening this important activity.

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In summary, the NTTF expressed its belief that "... voluntary industry initiatives could play a useful and valuable role in the suggested framework ...." These voluntary industry initiatives "... should not serve as a substitute for regulatory requirements but as a mechanism for facilitating and standardizing implementation of such requirements."

Relationship to RMTF Report 1

The RMTF report also expressed a concern regarding NRC's handling of industry voluntary initiatives in Finding PR-F-3: "The extent to which licensee activities undertaken as part of voluntary industry initiatives can be credited has been a source of contention in the Reactor Oversight Process and has reduced the efficiency of that process."

Detailed Description of Option

This option would clarify the role of voluntary industry initiatives in NRC's regulatory processes. It would define when or under what circumstances the NRC would incorporate such initiatives into regulatory requirements. The NRC would reiterate and better document the policy that voluntary initiatives should not be considered when deciding whether a regulatory action is necessary to provide adequate protection. In addition, the clarified guidance would emphasize that the NRC should monitor implementation of any voluntary initiative if it is a significant reason for not undertaking NRC regulatory action.

This option is being developed to address broader "industry initiatives," which are those affecting multiple licensees and generally coordinated by groups such as the Nuclear Energy Institute (NEI), owners groups, or other organizations working to resolve generic issues. Plant-specific initiatives or regulatory commitments are addressed using existing NRC and industry guidance documents related to the control of licensing basis information. As mentioned in the above quote from NUREG/BR-0058, matters related to ensuring adequate protection of public health and safety should not be left solely to voluntary programs and so the focus of this and previous efforts to develop the most effective and efficient regulatory processes, including providing a role for industry initiatives, focus on the those initiatives that deal with a means of complying with existing requirements (item 1 above) and those put in place in lieu of the NRC completing a regulatory action such as placing a new requirement into regulations (item 2 above).

A topic to consider in clarifying the role of industry initiatives is whether a new policy would be used for future decisions or whether the NRC staff would review past initiatives for possible incorporation into regulatory requirements. At this point, the NRC staff is not proposing actions except for those already being addressed in response to lessons learned from the Fukushima accident (i.e., reliable hardened containment vents for Mark I and II containments and improving various plant procedures (including SAMGs)). While it would be possible to revisit the development of regulations for some previous initiatives, the NRC staff considers such actions to be potentially disruptive unless pursued in concert with other improvement efforts (e.g., Option 2b described below).

The NRC staff considered two ways in which this option could be implemented:

(1) as a stand-alone improvement, and
(2) integrated with Options 3 and 4.

These two approaches are discussed below. The NRC staff recommends that the second approach (Option 2b) be taken if the Commission directs that Options 3 and 4 be pursued.

Option 2a: Stand-alone improvement

If this option was to be the only one chosen or was chosen to be pursued independently of other activities, the NRC staff would develop the necessary policies and procedures to ensure that the industry initiatives needed to ensure the desired outcomes were appropriately incorporated into one or more regulatory systems. The activity would include the preparation and issuance of specific policy and guidance documents, including:

- Commission Policy Statement
- Revision to Guidance Documents
    - Process Guidance such as Management Directors, Office Instructions, Inspection Procedures
    - NUREG/BR-0058 and related guidance

The above documents would define the Commission's policy on when or under what circumstances the NRC would impose explicit regulatory requirements (e.g., rules, orders, license conditions) relating to voluntary industry initiatives. The policy would re-affirm the Commission's direction not to use voluntary industry initiatives in lieu of regulatory action where a question of adequate protection exists. In addition, the policy would address the Commission's expectations for voluntary industry initiatives proposed to resolve issues not involving a question of adequate protection. In general, the staff expects that the guidance would include the following:

- Actions necessary to afford reasonable assurance of adequate protection of public health and safety or common defense and security shall be legally binding NRC requirements. Voluntary industry initiatives can be useful for developing common approaches or programs for how a regulatory requirement will be satisfied.
- For those issues being considered as a "cost-justified substantial safety improvement," voluntary industry initiatives are encouraged to help reach a common approach and expedite safety improvements. However, the staff will assess the initiative to determine if it should be incorporated into a regulatory requirement considering factors such as:
    - Importance in reducing or maintaining plants' risk profiles
    - Importance in maintaining plants' levels of defense-in-depth
    - Relationship of initiative to other regulatory requirements
    - Duration of initiative (e.g., one time or for remaining life of plants)
    - Degree of safety improvement achieved

- Some past voluntary initiatives have been proposed by industry in response to imminent regulatory action being contemplated by the NRC. When the NRC staff prepares its analysis that the burden associated with a proposed significant safety improvement is justified, it should (as is described as an option in current guidance) consider a base case assuming the absence or degradation of the voluntary industry initiative over time. If a backfit may be justified under such a scenario, the NRC should incorporate the initiative into a legally binding requirement to ensure the actions are implemented and maintained.

- In addition to incorporation of selected industry initiatives into regulatory requirements that are then subject to the NRC's routine inspection and oversight programs, the NRC should make greater use of the oversight processes (inspections, audits, significance determination process, *etc*.) to monitor the implementation and long-term effectiveness of voluntary industry initiatives (*i.e*., that have not been incorporated into a legally binding requirement) that are used for either a means to comply with a regulatory requirement or in lieu of the NRC imposing additional requirements. NRC could then take action (impose a legally binding requirement, *e.g*., issuance of rule or order (including license conditions)) as appropriate if the longer-term effectiveness of the voluntary initiative were being called into question.

In addition to developing a position or policy on licensee voluntary initiatives, this action could include an option to conduct a search for past voluntary initiatives to determine whether legally binding requirements should be issued for some or all. Examples of four industry initiatives and how they might be addressed under this option are provided below:

- Severe Accident Management Guidelines: These would likely be judged important to deliver and maintain a substantial safety improvement such that they should be maintained over the long term. Therefore, it is likely they would be imposed as a legally-binding requirement through development of an obligation (e.g., regulation, order, or license condition) or incorporation into a licensing basis document (e.g., final safety analysis report).

- Hardened Containment Vents: For certain containment designs, these would be judged important to maintaining a substantial safety improvement and would also be incorporated into a new or existing requirement.

- BWR Vessel and Internals Program (BWRVIP) and PWR Materials Reliability Program (PWRMRP) are examples of ongoing industry initiatives related to NRC regulated activities (pressure boundary integrity) that include periodic meetings, reports, and other interactions between licensees and the NRC staff. The programs include submittals to the NRC for review and approval as well as industry sponsored and NRC inspections. These initiatives are viewed as an example of industry efforts to effectively and efficiently comply with NRC requirements and have been effectively integrated into both licensee and NRC programs. The clarification of the role of industry initiatives should not undermine these effective programs.

- A fourth example relates to the monitoring of groundwater for minor levels of contamination (well below regulatory limits). The issue of groundwater contamination was identified at a number of U.S. nuclear power plants and involved many interactions between the NRC and stakeholders. The industry developed an industry initiative to improve monitoring and the Commission ultimately decided that the NRC need not revise its regulations to address this issue (but would instead acknowledge the industry initiative and only take action if it became apparent that the initiative was unsuccessful). The proposal here to clarify the role of industry initiatives would not seek to discourage such efforts as the groundwater initiative, which deals with leaks that have represented a small fraction of the limits NRC sets to maintain public health and safety and thus do not present a risk to the public.

Option 2b: Integrated improvement with other options

The issue of the proper handling of voluntary industry initiatives can also be addressed in conjunction with Options 3 and 4 related to balancing risk and defense in depth and the extension of regulatory requirements to better address beyond design basis events. Under this approach, the importance of an action implemented as part of an industry initiative would be assessed using the same guidance as would be used for other equipment and procedures assessed using the criteria and processes used to address Options 3 and 4. For example, a possible outcome from Options 3 and 4 is the creation of a new chapter within the Updated Final Safety Analysis Report (UFSAR) to address equipment and procedures important for providing protection from selected beyond design basis events. The items included in this new chapter would be subject to reporting requirements, change control processes, and other provisions important for implementing and maintaining parts of the licensing basis for a nuclear power plant. If a plant modification or procedure was pursued to address such beyond design basis events as part of an industry initiative, it would be incorporated into the UFSAR for each affected plant in accordance with the criteria for Options 3 and 4. For New Reactors, this type of an approach was developed to address the regulatory treatment of nonsafety systems for plants using passive design features. Using the same four examples as for the stand-alone approach to this issue, the likely outcomes of integrating this option with other activities are provided below (assuming initiative is not addressed by another regulatory vehicle such as rulemaking):

- Severe Accident Management Guidelines – It is likely that the SAMGs would be identified as an important part of the mitigation of various beyond design basis events captured in the design extension or design enhancement categories. Once identified as an important procedural control for events in the category, the SAMGs would be described in the licensing basis documents (e.g., FSAR Chapter 19) and be subject to the applicable reporting and change control requirements. The SAMGs would then also be subject to the normal NRC inspection and oversight processes.

- Hardened Containment Vents – as described above for SAMGs, the hardened containment vents and related procedures would be captured within the improved defense-in-depth criteria and the design extension/enhancement categories due to their importance in some beyond design basis events. Once recognized as an important feature for preventing or mitigating a design extension/enhancement event, the hardened vent would have been documented in a licensing basis document and subject to the applicable controls. The hardened vents would then also be subject to the normal NRC inspection and oversight processes.

- The BWRVIP and PWRMRP are incorporated into NRC processes that include NRC staff review and approval as well as industry and NRC inspections. The creation of a design extension/enhancement category would not likely change the current processes or documents.

- Groundwater monitoring – the revisions to the defense in depth and beyond design basis event category would not likely change the approach to the industry initiative for monitoring groundwater for minor levels of contamination.

Key Issues

- As mentioned above, a key issue is whether Option 2a would be only forward looking (i.e., apply to future decisions on handling initiatives) or if it would entail a review of previous industry initiatives (e.g., shutdown risk issues, etc.). It should be noted that this issue is not applicable to Option 2b since plant equipment or procedures would be captured by the improved defense-in-depth criteria and design extension/enhancement categories based on actual importance and not on whether the approach was or was not part of an industry initiative.

Expected Products

This activity would result in the following:

<u>Option 2a</u>

- Commission Policy Statement

- Management Directives, Office Instructions, and other guidance documents to implement this policy.

- Revisions to NRC's Regulatory Analysis Guidelines and procedures for preparing both plant-specific and generic backfit analyses for proposed new requirements and other regulatory actions.

- Revisions to inspection manual to better address industry initiatives

- If the Commission directs that this policy be retroactive, a listing of licensee voluntary initiatives currently in place would be developed. Each of these would be analyzed in terms of the policy criteria and the backfit rule. Appropriate legally binding requirements would be promulgated consistent with these analyses.

<u>Option 2b</u>

- If pursued in concert with Options 3 and 4 (Option 2b), there would be little or no additional products needed for voluntary industry initiatives since this topic would be addressed within the larger efforts related to defense in depth and development of a design extension/enhancement category.

Pros and Cons for this Option

Pros

- Would clearly set forth criteria for determining when and how voluntary industry initiatives would be integrated into regulatory processes

- Would clarify to all stakeholders how voluntary initiatives fit into the NRC's regulatory framework

- Would define how industry initiatives should be addressed within NRC inspection and oversight processes.

- Would ensure that the safety benefits derived from voluntary licensee initiatives would be consistently maintained over time.

- Related processes would address desire for monitoring and feedback to ensure the voluntary initiatives (whether used in lieu of or to support implementation of regulatory requirements) were implemented, maintained, and delivering the desired results in terms of plant safety.

Cons

- For stand-alone option, licensees may be discouraged from proposing solutions to regulatory issues if NRC will issue a legally binding requirement in spite of such voluntary proposals.

- The absence of voluntary initiatives or the need to incorporate such initiatives into regulations may delay development and implementation of safety improvements.

Estimated Resources

Industry implementation costs (104 plants)	$1,201,000
NRC implementation costs	$460,000
Total implementation costs	$1,661,000

Option 3 - Establish a Decision Process for Balancing Risk, Defense-in-Depth, and Safety Margins

SUMMARY OF OPTION

This option would establish the Commission's expectations with regard to risk-informed regulatory decision process for balancing risk, defense-in-depth, and safety margins. It would define the objective of and the principle elements of defense-in-depth and safety margins. It would establish a risk-informed, regulatory decision process for balancing risk, DID and safety margins. This would include the NRC developing criteria for determining whether adequate defense-in-depth and safety margins have been addressed in the design and operation of a nuclear power plant.

BACKGROUND

The NRC has made progress towards implementing risk-informed regulation. Although initial successes have indicated the usefulness and importance of using risk insights to inform regulatory decisions, principles of risk-informed regulation have not been incorporated into the overall regulatory framework for power reactors in a comprehensive manner. Five key principles of risk-informed regulation have been specified in Regulatory Guide 1.174, which provides guidance for licensees to voluntarily request risk-informed license amendments, but not for other types of risk-informed decisions. Moreover, these five key principles of risk-informed regulation are not well-defined in a manner that facilitates regulatory decision-making.

Regulatory Guide 1.174 set forth five key principles of risk-informed decisionmaking:

- The proposed change meets the current regulations unless it is explicitly related to a requested exemption.
- The proposed change is consistent with a defense-in-depth philosophy.
- The proposed change maintains sufficient safety margins.
- When proposed changes result in an increase in CDF or risk, the increases should be small and consistent with the intent of the Commission's Safety Goal Policy Statement.
- The impact of the proposed change should be monitored using performance measurement strategies.

The Regulatory Guide provides guidance on defense-in-depth, safety margins, and risk only as they relate to the proposed change; that is, it is assumed that the original plant design has achieved acceptable levels of each of these attributes.

NRR Office Instruction LIC-504, "Integrated Risk-Informed Decision-Making Process for Emergent Issues," uses these same five key principles in a decision process. However, LIC-504 applies only for emergent issues where no other NRC process exists to resolve the issue.

Because defense-in-depth, safety margins, and risk are key to this option, the history of each is discussed below.

Defense-in-Depth

Since the beginning of licensing nuclear facilities, the concept of defense-in-depth has been an integral part of the regulatory framework regardless whether the term defense-in-depth was used. Starting with WASH-740 in March 1957, "Theoretical Possibilities and Consequences of Major Accidents in Large Nuclear Power Plants," the concept of multiple lines of defenses was introduced: *"Looking to the future, the principle on which we have based our criteria for licensing nuclear power reactors is that we will require multiple lines of defense against accidents which might release fission products from the facility."* This concept of multiple lines of defense, over time, has been consistently viewed for describing defense-in-depth. It has been generally characterized in terms of multiple barriers, levels of defense, levels of protection, successive compensatory measures, lines of protection, multiple measures, protective barriers, echelons of defense, etc. Moreover, levels of defense have been viewed as an approach to address accident prevention and mitigation. This consistency can be seen in the three following examples regarding the different, but similar, explanations for levels of defense:

- preventing accidents from occurring, having safety systems in place should an accident occur, having mitigation capabilities in place should the safety systems not function, having emergency plans in place if mitigation does not work

- successive barriers which include accident prevention, safety systems, containment, accident management, siting and emergency planning

- three successive protective barriers which include preventing initiation of incidents (conservative design margins, etc.), capability of detecting and terminating incidents, and protecting the public.

In further reviewing the history, there has been a consensus in that defense-in-depth is needed to compensate for the recognized lack of knowledge (i.e., uncertainties) regarding nuclear reactor operations and the consequences of potential accidents. That is, defense-in-depth is needed to deliver a design that is tolerant of uncertainties in our knowledge regarding plant behavior, component reliability, or operator performance that might compromise safety. Moreover, given the uncertainties, if a failure should occur it would be compensated for or corrected without causing harm to individuals or the public at large. In summary, there has been a common theme with regard to defense-in-depth which is to prevent and mitigate accidents via multiple levels of defense in light of uncertainties to keep the risk to an acceptable level. However, although the levels of defense address accident prevention and mitigation, how to implement a level of defense has not been consistently viewed. The tactics for implementing the various levels have included for example:

- reactor core, reactor vessel, reactor container

- quality in design, safety systems, consequence-limiting systems

- quality assurance, protective systems, engineered safety features

- safety margins, high quality, redundancy, containment structure and safety features, emergency plans

The above discussion presents a deterministic approach to defense-in-depth. The deterministic model to defense-in-depth is embodied in the structure of the regulations and in the design of the facilities that are built in accordance with those regulations. The potential requirements for defense-in-depth result from repeatedly asking the question, "What if this barrier or safety feature fails?" regardless of the quantitative estimate of the likelihood of such a failure. Therefore, a characteristic of this approach is that there is reliance on each line of defense to protect against the unknown and unpredictable; e.g., assuming the other defenses have not succeeded.

A probabilistic approach to defense-in-depth came into the history in the mid 1990's and it acknowledged PRA as a powerful tool in searching for the unexpected and identifying uncertainties. It recognized that although PRA cannot compensate for the unknown and identify all unexpected events, a probabilistic approach could use risk assessment to: (1) identify some originally unforeseen scenarios, (2) identify where some of the uncertainties lie in the plant design and operation, and, for some uncertainties, (3) quantify the extent of the uncertainty. In other words, while the PRA may not be helpful in reducing uncertainties associated with the PRA itself, it can point out areas where "deterministic defense-in-depth" needs enhancement.

With moving to a risk-informed regulatory framework, PRA could play a role in defense-in-depth. The discussion in the *Federal Register* Notice (FRN) that promulgated the Commission PRA Policy Statement (1995) notes that "PRA technology will continue to support the NRC's defense-in-depth philosophy by allowing quantification of the levels of protection and by helping to identify and address weaknesses or overly conservative regulatory requirements." The FRN discussion also notes that defense-in-depth is used by the NRC to provide redundancy as well as a multiple-barrier approach. Risk insights could be used to move to a more structured, formal process in implementing and evaluating the adequacy of defense-in-depth.

The use of risk to help assess whether adequate defense-in-depth has been achieved came into the history in the 2000-2012 time frame. IAEA and INL, in particular, have proposed risk as one of the measures to assist in determining adequacy of defense-in-depth. For example,

- quantitative safety goal targets are established for each level of defense using a frequency consequence curve; plant design and operation is evaluated against each level to determine if the quantitative target goal has been met

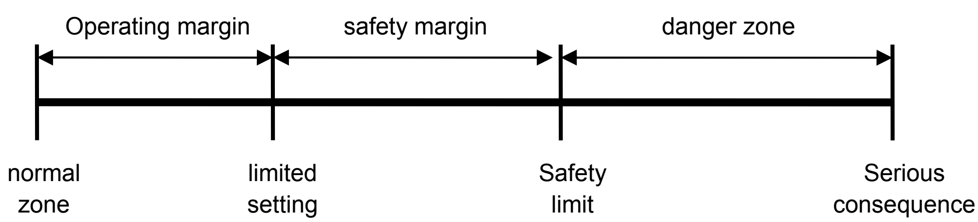
- decision process with criteria is established that evaluates whether quantitative criteria (using a frequency consequence curve) have been met while also determining whether there is adequate safety margins and if the known uncertainties have been adequately addressed

<u>Safety Margins</u>

The concept of safety factor or safety margin is a key principle in balancing risk and defense-in-depth. It's definition needs to be commonly understood. One definition of the English word "margin" is "an amount allowed beyond the necessary," and its use in engineering is typically associated with the gap or distance between the expected value of a parameter and the value that would result in an undesired result; e.g., failure of a component. Consequently, by including margin in the design, it allows the SSC to perform past it operating limiting to a certain level without negative consequences.

The Commission's regulations require that SSCs have adequate margins of safety. The concept of margin is built in to the various engineering codes and standards in virtually all engineering disciplines. The General Design Criteria 2, 10, 15, 26, 27, 31, 50 and 51 explicitly require that sufficient margin be provided in the design of specific SSCs. Other regulations implicitly or explicitly call for safety margins in the designs of nuclear power reactors.

Appendix D to AEC-R2/20, "Guide to Content of Technical Specifications for Nuclear Reactors," (June 30, 1966), includes a discussion of safety margins. Although the discussion is related to technical specifications, the discussion is useful to illustrate the concept of safety margin. That document describes three types of margin. First, there is margin between a safety limit and the unknown area where failure or serious consequences could occur: Margin between the safety limit and the "danger zone" provides allowance for uncertainty in the onset of damage or consequences. The safety margin is defined as the allowance between limiting safety system settings and the safety limit. This margin allows for safety system action plus calibration uncertainties and instrument inaccuracies. Finally, the margin between the normal operating zone and the limiting safety system settings is called operating margin. This allows for such things as instrument drift and other minor operational errors and fluctuations in process or control characteristics. This concept is illustrated below:



SRM/SECY-98-144, "White Paper on Risk-Informed and Performance-Based Regulation," includes the concept of safety margin in its definition of "Risk-Informed, Performance-Based Approach:"

> "A risk-informed, performance-based approach to regulatory decision-making combines the "risk-informed" and "performance-based" elements discussed … above, and applies these concepts to NRC rulemaking, licensing, inspection, assessment, enforcement, and other decision-making. Stated succinctly, a risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment including the principle of defense-in-depth and the incorporation of safety margins, and performance history are used, to (1) focus attention on the most important activities, (2) establish objective criteria for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, (4) provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes, and (5) focus on the results as the primary basis for regulatory decision-making."

A definition of safety margins relevant to nuclear power reactors may also be found in a recent report on the Fukushima event of March, 2011, by the ASME:

> "Engineers provide design margins in the deterministic approach to nuclear power plant design, much like engineers provide margins in other designs, such as bridges and airplanes. A design margin is the distance between the bounding prediction of a load or

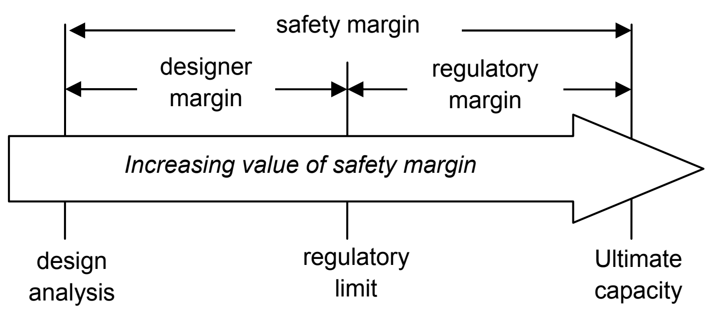
other condition and the point at which the potential for failure due to that condition becomes non-negligible. Design margins, usually called safety margins when discussing specific nuclear safety-related issues, help account for uncertainties and unknowns, as well as wear and tear, e.g., corrosion or cyclic fatigue of a pipe.

In the deterministic approach to design of nuclear power plants, safety margins are included in selection of design methods, design criteria, codes and standards, and operating limits. … ”

NUREG-1860 also provides a discussion on safety margins.

“Safe operating conditions can be characterized by maintaining limits on one or more safety variables, such as pressure and temperature, etc. . .   Safety margins are linked to safety limits—limiting values imposed on safety variables (e.g., peak clad temperature (PCT) and containment pressure in current LWRs). Thus, when operating conditions stay within safety limits, the safety barrier or system continues to function, and an adequate safety margin exists. The intent is to allow margin for phenomena and processes that are inadequately considered or neglected in the analysis predicting the behavior of the given system or physical barrier.

For the definition of safety margin in this report, the safety variable is assumed to have an ultimate capacity, beyond which the safety system or barrier fails, e.g., the ultimate strength of a critical barrier. A regulatory limit is set on the safety variable, well below this capacity, to ensure that the ultimate capacity is not reached during normal operation as well as excursions from normal operation. The difference between the ultimate capacity and the regulatory limit is termed the “regulatory margin” here. The designer can incorporate an additional margin, called the “operational margin” here, by designing the system so it operates well below the regulatory limit for normal operations and excursions. Together the regulatory margin and the operational margin constitute the safety margin. Figure 4-3 shows this definition.”



In reviewing the history regarding safety margin, there appears to be a similar concept in that safety margins provide a layer of protection regarding the uncertainty for when the SSC actually fails to function. However, the extent of margin required and where margins should be applied have not been developed. This view of safety margin becomes important when describing a process that balances risk information, defense-in-depth and safety margins. For example, the level of defense may or may not be sufficient depending on the amount of safety margin incorporated into the performance of the SSCs under consideration. In making safety decisions, the ability to ensure adequate defense-in-depth and adequate safety margins are maintained is essential. Regulatory Guide 1.174 does provide a brief discussion on the adequacy of safety margins. It states that there is sufficient safety margins when:

- Codes and standards or their alternatives approved for use by the NRC are met.
- Safety analysis acceptance criteria in the LB (e.g., FSAR, supporting analyses) are met or proposed revisions provide sufficient margin to account for analysis and data uncertainty.

Risk Assessment

A key factor in balancing defense-in-depth, safety margins, and risk is the use of risk assessment techniques. The most comprehensive approach to assessing the risk of a nuclear power plant at present is a PRA. All operating nuclear reactors at present have a plant-specific, internal events, core damage and large-early release PRA; however, ensuring the specified scope, level of detail, and technical adequacy of the PRA is sufficient to support its use is a major factor. New reactors are required by 10 CFR 50.71(h) to develop, maintain, and periodically upgrade a Level 1 and a Level 2 PRA until the permanent cessation of operations. The required scope of the PRA is defined (initiating events and modes for which NRC-endorsed consensus standards on PRA exist). Its technical acceptability is specified in Regulatory Guide 1.200 which includes NRC endorsement of the published PRA standards.

There are no similar requirements for reactors licensed under Part 50 (currently operating reactors). However, risk-informed initiatives both required (e.g., 10 CFR 50.65) or voluntary (10 CFR 50.69) have used results from a PRA. The current guidance addressing the scope, level of detail, and technical adequacy of a PRA is provided in RG 1.200 which describes the process to be used to assess PRA technical acceptability. It references consensus standards (as endorsed by the staff) to be used to define and measure technical acceptability.

RELATIONSHIP TO NTTF RECOMMENDATION 1

This option is directly related to NTTF Recommendation 1which states: "The Task Force recommends establishing a logical, systematic, and coherent regulatory framework for adequate protection that appropriately balances defense-in-depth and risk considerations." Development of potential decision criteria for assessing when defense-in-depth has been adequately addressed in the design of a nuclear power plant would be the first step in implementing the NTTF's recommendation.

In Recommendation 1 of the NTTF report, that task force provided its definition of defense-in-depth:

> "The key to a defense-in-depth approach is creating multiple independent and redundant layers of defense to compensate for potential failures and external hazards so that no single layer is exclusively relied on to protect the public and the environment. In its application of the defense-in-depth philosophy, the Task Force has addressed protection from design-basis natural phenomena, mitigation of the consequences of accidents, and EP."

The NTTF referred to the margin requirement in GDC 2 in its recommendations related to protection from design-basis natural phenomena. The NTTF stated, "Failure to adequately protect SSCs important to safety from appropriate design-basis natural phenomena with appropriate safety margins has the potential for common-cause failures and significant consequences as demonstrated at Fukushima."

The NTTF concluded that a more balanced application of the Commission's defense-in-depth philosophy using risk insights would provide an enhanced regulatory framework that is more logical, systematic, coherent, and better understood. Such a framework would support appropriate requirements for increased capability to address events of low likelihood and high consequence, thus significantly enhancing safety. The NTTF described a new regulatory framework where risk assessment and defense-in-depth would be combined more formally. The NTTF concluded that the new framework could be implemented on the basis of full-scope Level 1 core damage assessment PRAs and Level 2 containment performance assessment PRAs.

RELATIONSHIP TO RMTF REPORT

The RMTF notes in NUREG-2150 that "After decades of use, there is no clear definition or criteria on how to define adequate defense-in-depth protections." The RMTF further notes that "the concept of defense-in-depth has served the NRC and the regulated industries well and continues to be valuable today. However, it is not used consistently, and there is no guidance on how much defense-in-depth is sufficient." The RMTF concluded that "clarifying what the U.S. Nuclear Regulatory Commission (NRC) means by defense-in-depth is a necessary part of the development of a holistic strategic vision."

The RMTF described safety margins in various places in NUREG-2150, for example:

> "The traditional approach used by the NRC and industry to provide confidence in a reactor design's defense-in-depth capabilities is based on analyzing stylized accident scenarios using approved conservative codes and criteria. The conservatisms added to design limits, acceptance criteria, and safety margins are intended to manage the uncertainties associated with accidents, including possible "unknown unknowns," at the time a plant was designed. Safety margins are included in the analyses such that specific barriers are designed and constructed to ensure actual failures are not expected until key parameters well exceed the values assumed in the supporting engineering evaluations."

In describing risk-informed, performance-based regulation, and safety margins the RMTF states:

> "Within the above construct of risk-informed and performance-based defense-in-depth for power reactors, safety margins refer to conservatisms added to ensure that plants and specific barriers are designed and constructed so that failures are not expected until key parameters well exceed the values assumed in the supporting engineering evaluations. Safety margins usually derive from the traditional approach to design-basis accidents, but they can be informed by risk assessment techniques. Measures to address the reliability of barriers and supporting systems have increasingly been introduced to the regulatory process for power reactors (e.g., maintenance rule and reliability assurance programs for new reactors), but additional improvements for establishing and monitoring reliability goals could be developed for some equipment considered important to safety (e.g., equipment used in response to the loss of large areas due to fires or explosions). The improvements related to reliability have resulted largely from risk assessments and their use in programs such as the Reactor Oversight Program."

DETAILED DESCRIPTION OF OPTION

The Commission would issue a policy statement that would articulate the Commission's views on the need to balance risk, defense-in-depth, and safety margins. It would clearly describe the need for defense-in-depth, its objectives, and the strategy to be taken for defense-in-depth. In spite of the long-term and widespread use of safety margins in the design of nuclear power reactors, the Commission has not explicitly defined the term safety margin. The policy statement would also clearly describe the need for safety margins, and explicitly define its objectives, and the elements and principles related to safety margins. Along with the policy statement, the NRC would establish a decision process that would provide guidance for balancing risk, defense-in-depth and safety margins. This would include the NRC developing criteria for determining whether adequate defense-in-depth and safety margins have been addressed in the design and operation of a nuclear power plant while using risk insights.

Policy Statement

The policy statement would explain what is meant by balancing risk, defense-in-depth and safety margin. Because the ultimate goal is that the overall risk to public health and safety be acceptably low, a proper "balance" might be inclusion of adequate margins and levels of defense such that the calculated risk is small and additional features are provided to account for uncertainties. For example, balancing could involve integrating defense-in-depth and safety margins into the design and operation of the plant using risk insights; this balancing would:

- compensate for uncertainties, including events and event sequences which are unexpected because their existence remained unknown during the design phase,
- compensate for potential adverse equipment performance, as well as human actions of commission (intentional adverse acts are part of this) as well as omission,
- maintain the effectiveness of barriers and protective systems by ensuring multiple, generally independent and separate, means of accomplishing their functions, and
- protect the public if these barriers are not fully effective.

The policy statement would reinforce the Commission's expectation that all regulatory decisions be made with appropriate consideration of uncertainties. The approach or strategy proposed in the policy statement for defense-in-depth and safety margins would be a risk-informed approach in that it would include both deterministic and probabilistic criteria. The policy statement would clearly state that the deterministic criteria for defense-in-depth and safety margins must, at the most fundamental level, compensate for all uncertainties, including those in the PRA models or other risk assessments.

As an example, the deterministic defense-in-depth elements identified and described in the policy statement could be:

1. Specifying three specific levels of defense to ensure the risk would be acceptably low, for example,

    - Level of Defense 1: Accident Prevention to ensure that there is (1) stable operation to limit the frequency of events that can upset plant stability and challenge safety functions and (2) protective systems to ensure that the systems are adequately designed, and perform adequately, in terms of reliability and capability, to satisfy the design assumptions on accident prevention during all states of reactor operation.

- Level of Defense 2: Barrier Integrity to ensure that there are adequate barriers to protect the public from accidental radionuclide releases from all sources. Adequate barriers could include physical barriers as well as the physical and chemical form of the material that can inhibit its transport if physical barriers are breeched.

- Level of Defense 3: Accident Mitigation to ensure that adequate protection of the public health and safety in a radiological emergency can be achieved should radionuclides penetrate the barriers designed to contain them.

2. Requiring that the levels of defense would be maintained; that is, independent of risk, in balancing risk and defense-in-depth and safety margins, each of the levels of defense need to be met. For example:

   - Requiring that accident prevention alone could not be relied on to reach an acceptable level of safety, and

   - Requiring that the capability to mitigate accidents would also be needed.

The probabilistic elements identified and described in the policy statement could consist of using the PRA, (1) to the extent possible, to search for and identify unexpected scenarios, including their associated uncertainties, (2) to subsequently establish adequate defense-in-depth measures to compensate for those scenarios and their uncertainties which are quantified in the PRA model. The ability to quantify risk and estimate uncertainty using PRA techniques, where possible, and taking credit for defense-in-depth measures in risk analyses, allows one to provide a better estimate of how much defense-in-depth is enough. In this manner PRA complements defense-in-depth.

The information contained in the policy statement would use the information provided in Enclosure x.

Implementing Guidance

Along with the policy statement, the NRC would establish the necessary guidance for making risk-informed regulatory decisions. The guidance would likely include a Management Directive other documents (e.g., regulatory guides, NUREGs, SRP chapters) for a process that would involve decision-based criteria for implementing the defense-in-depth strategy and for determining adequate defense-in-depth has been achieved. The guidance would also use the information provided in Enclosure x.

The implementing criteria would involve examining each level of defense to identify key design and operational features for consideration (e.g., redundancy and diversity). The adequacy criteria would also involve each level of defense and would include both deterministic and probabilistic acceptance guidelines. That is, for determining if adequate defense-in-depth has been achieved, there would be a blended deterministic and probabilistic process that defines both deterministic and risk criteria. Examples of probabilistic criteria could include:

- quantitative health objectives, core damage frequency, large early release frequency, or other societal measure

- system reliability goals – the system (i.e., level of defense) could be analyzed using PRA methods to determine whether established reliability goals are met

- the uncertainties in the analysis could be evaluated, especially those due to model incompleteness, and determine what steps should be taken to compensate for those uncertainties.

In determining whether adequate defense-in-depth has been achieved, the use of risk is an integral part; however, the extent of defense-in-depth that is needed can be impacted by safety margins. For example, a tactic in achieving one of the levels of defense is a particular design feature. Whether this feature has safety margin and the extent of the margin can influence the degree to which the feature plays in defense-in-depth. Consequently, determining the adequacy of defense-in-depth can be dependent on safety margins and the associated risk. Therefore, the process for determining adequacy should balance risk, defense-in-depth and safety margins. The process could include, for example, the following:

- For a given level of defense, develop quantitative criteria. For example, consider the Accident Mitigation level of defense, proposed quantitative criteria could be in the form of a frequency-consequence curve. The risk would be evaluated considering the mitigation measures put in place against the curve. The evaluation would consider any safety margins in the assessment, whether the uncertainties have been addressed. If in the decision process, it has been determined that one of the decisions have not been adequately addressed, then plant defense-in-depth capabilities and the programmatic assurance could each enhanced and the entire decision criteria would then be re-evaluated.

KEY ISSUES

There are several issues which the Commission should address as part of this option:

- Should the regulatory analysis guidelines and backfit analysis guidelines include defense-in-depth and safety margins as fundamental decision criteria?

- The policy statement and MD would provide the criteria for how defense-in-depth should be implemented. However, determining if an individual licensee has adequate defense-in-depth is determined on a plant-specific basis. The most efficient approach would be to use a plant-specific PRA. Moreover, one level of defense would involve emergency planning and the potential acceptance guidelines could involve consequences. This would require the use of a Level 3 PRA.

EXPECTED PRODUCTS

Under this activity, the staff would develop the following for Commission approval:

- Commission policy statement(s) that includes:

- Discussion on Commission's expectations regarding the need to use risk-informed regulatory decision making that balances risk, defense-in-depth and safety margins; would include an explanation of what is meant by balancing risk, defense-in-depth and safety margin.

- Explicit description of defense-in-depth that would include the objective and need for defense-in-depth, along with the strategy to be used for accomplishing defense-in-depth (e.g., multiple barriers, level of defense).

- Explicit definition of safety margin as it applies to nuclear power plants.

- Explanation of how defense-in-depth and safety margins compensate for uncertainty.

- Commission expectations regarding having and maintaining plant-specific PRA models (may require rulemaking if a new requirement is desired by the Commission).

- Description of how the current PRA Policy statement supports the promulgation of regulations or a new Policy Statement and associated SRM directing the transition of the NRC to risk-informed regulatory decision making process, including a schedule for key events and activities

• Implementing guidance (e.g., Management Directive) that includes:

  - Decision criteria for implementing the strategy for achieving defense-in-depth and associated decision criteria for determining whether adequate defense-in-depth has been achieved.

  - Decision criteria for evaluating whether sufficient safety margin exists in the design of a nuclear power plant.

  - Scheme for integrating risk insights with defense-in-depth and safety margins (e.g., explanation of how risk and safety margins are considered in determining acceptable defense-in-depth).

  - Revision to the Regulatory Analysis Guidelines based on defense-in-depth criteria and risk assessment.

  - Conforming changes to existing regulatory guides

PROs and CONs of this Option

<u>PROs</u>

• Supports Commission policy statement on the increased use of PRA in all regulatory matters.

• Supports Commission's strategic plan on safety and organizational excellence.

• Could reduce unnecessary regulatory burden.

- Supports principles of good regulation.

- Makes decisionmaking process more objective and more uniform.

- Would facilitate more timely NRC decisionmaking.

- Would allow important safety decisions to be made on more than just a risk basis; e.g., filtered vents for Mark I and Mark II containments.

CONs

- Significant resource expenditures would be incurred which might not result more than a moderate increase in plant safety

ESTIMATED RESOURCES

Industry implementation costs (no PRA upgrade) (108 plants)	$1,235,000
NRC implementation costs	$1,038,000
Total implementation costs	$2,273,000

Option 4a – Establish a design-basis extension category on a generic basis

Summary of Option

This activity would expand the current categories of plant accidents and events which must be considered when determining NRC safety requirements. In addition to the current set of design-basis accidents, this activity would add a design-extension category, which would include accidents with significant consequences which are not included in the existing deterministic design-basis accidents (DBAs). NRC would specify a set of design-extension events (DEE) on a generic basis. Development of a plant-specific PRA for the purpose of identifying these events would not be a regulatory requirement.

Background

The Concept of Design Basis and Design Basis Events

The Commission has historically relied upon a set of design-basis events and accidents to demonstrate that a nuclear plant design is robust. Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants.", provides a list of potential accident initiating events (initiators) that applicants are requested to address in Chapter 15 of the Safety Analysis Report. The loss of coolant accident (LOCA) is specified in 10 CFR Part 50 as the design-basis for the light water reactor (LWR) emergency core cooling system and containment, and the performance of these SSCs is evaluated and reported in Chapter 6 of the FSAR. The term “design basis accident” (DBA) is defined as a postulated set of failure events that a facility is designed and built to withstand without exceeding the offsite exposure guidelines in §50.34(a)(1) or §100.11 of the Commission’s regulations.

NUREG/CR-6042, "Perspectives on Reactor Safety," provides the long history of the concept of design-basis for nuclear power plants. Yet, despite the long history of this regulatory concept, important “design-basis” terms have not been consistently defined or clearly distinguished from other regulatory requirements in 10 CFR 50. Although “design bases” is defined in 10 CFR 50.2, “design-basis event” and “design-basis accident” are not, even though both terms are used in many places in Part 50.

Option 4a, as described below, does *not* involve developing a revised regulatory construct for design-basis accidents and events. The staff acknowledges that the portion of the NRC’s existing regulatory framework addressing design-basis events and accidents for nuclear power plants is complex and could be clarified to be more understandable to NRC staff and external stakeholders.. Nonetheless, the staff agrees with the NTTF that the existing framework has provided adequate protection. Option 4a is limited to establishing regulatory requirements for addressing the new design-extension events, as recommended by NTTF Recommendation 1.1. However, the staff believes that to do this in a clear manner, it may be necessary to include the definition of design-basis event and design-basis accident in the regulations so as to make clear the distinction between them and DEE.

Events Outside the Design Basis

Chapter 3 of the NTTF report provides a discussion of the historical development of requirements to address issues beyond the design-basis which will not be repeated here. In summary, The NRC has adopted requirements addressing new events based on new information (*e.g.*, risk insights from IPE/IPEEE, plant events, operating experience) without a common set of criteria for characterizing these events using the DBA/DBE nomenclature. Some examples include the SBO Rule, 10 CFR 50.63, the Electrical Equipment Qualification Rule, 10 CFR 50.49 and Aircraft Impact Assessment Rule, 10

CFR 50.150. In addition, the NRC has relied upon industry or individual licensee voluntary actions to address issues identified by the NRC as the result of new information, but without characterizing these issues using the DBA/DBE nomenclature.

As noted below, both the NTTF and the RMTF have recommended that the Commission consider establishing a category of extended or enhanced design-basis accidents or events to augment the existing NRC regulatory framework for reactors. Additionally, several international industry and regulatory organizations have already made requirements to consider beyond-design-basis events explicitly. The Western European Nuclear Regulators Association (WENRA) now recommends a “design-extension” analysis and the International Atomic Energy Agency (IAEA) has included a requirement in a draft safety requirements document[1] for identification of “design-extension conditions. In both cases events are selected based on deterministic and probabilistic assessments, and engineering judgment and power plants are expected to have measures for prevention or mitigation of the events.

Relationship to NTTF Recommendation 1

The NTTF considered the current NRC regulatory framework as one that “ … has come to rely on design-basis requirements and a patchwork of beyond-design-basis requirements and voluntary initiatives for maintaining safety.” The NTTF observed that “… for new reactor designs, the Commission’s expectations that beyond-design-basis and severe accident concerns be addressed and resolved at the design stage are largely expressed in policy statements and staff requirements memoranda, only reaching the level of rulemaking when each design is codified through design certification rulemaking.” The NTTF supported a more formal approach that would include “extended design-basis events” in a new regulatory framework:

> The Task Force envisions a framework in which the current design-basis requirements (i.e., for anticipated operational occurrences and postulated accidents) would remain largely unchanged and the current beyond-design-basis requirements (e.g., for ATWS and SBO) would be complemented with new requirements to establish a more balanced and effective application of defense-in-depth.

The NTTF report goes on to say:

> This framework, by itself, would not create new requirements nor eliminate any current requirements. It would provide a more coherent structure within the regulations to facilitate Commission decisions relating to what issues should be subject to NRC requirements and what those requirements ought to be. … Such changes would establish a more logical, systematic, and coherent set of requirements addressing defense-in-depth.

Relationship to RMTF Report

The RMTF explicitly recommends the creation of a special category of events that are beyond the current design-basis events, called “design-extension events:”

The purpose of the design-extension category is to address gaps that exist between the regulatory controls that are appropriate to address the risk management goal (e.g., risk-

[1] DS414, “Safety of Nuclear Power Plants”

informed, performance-based defense-in-depth) and current controls involving a combination of design-basis events and ad hoc requirements added in reaction to specific events or other concerns. The goal would be to define a consistent approach for such events in terms of analysis techniques, safety classification, change control, reporting, and other regulatory requirements that have been defined previously on a case-specific basis. … [the RMTF] envisions that the combination of design-basis events, design-extension events, and various programs such as emergency preparedness collectively define the risk-informed and performance-based defense-in-depth protections that are the centerpiece of the proposed Risk Management Regulatory Framework.

Detailed Description of Option

This option would, by regulation: (i) add a design-extension category of events to be included in the NRC's regulatory framework for nuclear power plants and specify the attributes of such events and accidents; (ii) identify the set of NRC technical regulations that address design-extension events and accidents; (iii) establish the "regulatory treatment requirements" applicable to the systems, structures and components, and power plant activities addressed by the NRC-designated set of design-extension regulations; and (iv) require applicants and licensees for nuclear power plants (including applicants for design approvals and design certifications under Part 52) to comply with applicable design-extension requirements and to include in applications and FSAR updates (as applicable) information necessary for the staff to determine if there is reasonable assurance the requirements are met. The new requirements would specify analysis methods, assumptions, and acceptance criteria for demonstrating the ability to mitigate these design-extension events, as well as minimum treatment requirements for the involved equipment and procedures. The new categorization requirements would be imposed on existing nuclear power plants (including already-approved design certifications and combined licenses, as well as future plants (including applications currently in process).

Design Extension Category Description

The NRC would adopt a new *design-extension* category supplementing the current *design-basis event* and *design-basis accident* categories of plant events and accidents and events for which a nuclear power plant must be designed, constructed and operated.[2] At this time, staff believes that the category would be described in § 50.2, *Definitions*. The definition would set forth the high-level attributes (criteria) of plant events and accidents to be considered design-extension. These attributes would be used by the NRC as part of the rulemaking establishing the design-extension concept in order to designate existing NRC regulations as addressing design-extension events and accidents (*see* discussion in the next section, *NRC Designation of Generic Design Extension Category Events and Accidents)*. These attributes would also be used by the NRC in the future to help determine whether new (or amended) regulatory requirements adopted on the basis of new information, are to be categorized as design-extension.

The high-level attributes for designating events and accidents as design-extension could be based upon risk, defense-in-depth, and avoidance of "cliff-edge" effects associated with occurrence of internal and external hazards that exceed the existing deterministic design bases.

[2] The staff notes that the design-extension requirements, as well as the applicant's/licensee's "commitments" for compliance with these requirements, will be considered to be part of the "design-basis" for the plant. As discussed later in this Enclosure, these "commitments" will be required by regulation to be described in the FSAR or the equivalent DCD.

Implementing details would be established in NRC guidance documents. This approach would provide regulatory stability and transparency with respect to the overall design-extension concept, but allow the NRC some flexibility in developing, implementing and evolving the details of the concept without going through notice and comment rulemaking.

The overarching technical and policy issue is whether the design-extension category should be regarded as an adequate protection requirement, or whether it represents an "enhanced" level of safety beyond that needed for adequate protection. Resolution of that issue could affect the selection of attributes describing the design-extension category of events and accidents. The NTTF recommended that "design-extension" events – which may be considered to be comparable to design-extension events - be regarded as adequate protection, see NTTF Recommendation 1.1. The NRC staff agrees with the NTTF that the design-extension events should be those necessary for adequate protection. Substantial safety improvements which would be backfit on licensees using the current NRC regulatory approach (10 CFR 50.109) would not be classified as design-extension events. Although Option 4a would not categorize these additional protection requirements, the Commission could, at an appropriate time in the future, choose to do so.

The staff notes that this option is limited to establishing a description and regulatory requirements for addressing the new design-extension category, as recommended by NTTF Recommendation 1.1. It does *not* involve developing an analogous regulatory construct for design-basis accidents and events. The staff acknowledges that the portion of the NRC's existing regulatory framework addressing design-basis events and accidents for nuclear power plants is complex and has evolved over time and may not be as logical, consistent or coherent as a framework developed all at once. Nonetheless, the existing framework for design-basis events and accidents is well understood by NRC and licensees. The staff agrees with the NTTF that the existing framework has provided adequate protection. Therefore, it seems prudent to first gain experience with developing and implementing the new design-extension categorization scheme. Once the NRC has completed implementation of this option and gained some experience, the Commission may assess whether there is sufficient regulatory value to develop an analogous regulatory construct for design-basis accidents and events.

NRC Designation of Generic Design Extension Category Events and Accidents

The NRC would specify, by regulation, a *generic* set of events and accidents which are to be regarded as falling within the design-extension category, by listing the existing NRC regulations which address events and accidents to be regarded as design-extension events and accidents (e.g., 10 CFR 50.63, station blackout, etc.) and potentially, events not currently addressed in regulations (e.g., loss of decay heat removal in pressurized water reactors during refueling with reduced inventory and fuel in the reactor vessel). In screening generic plant events and accidents, and existing regulatory requirements for potential designation as generic design-extension, the staff recommends that the design-extension category encompass the full range of plant conditions, including startup, shutdown, and normal operation. In addition, the staff recommends that the generic designation activity be informed by a review of information already collected by the NRC from the following:

- Individual Plant Evaluations and the Individual Plant External Event Evaluations

- Analyses performed with NRC SPAR models

- Accident Sequence Precursor Analyses performed by the NRC
- PRAs which have been performed by existing nuclear power plant licenses and design certification applicants
- State-of-the-Art Reactor Consequence Analysis (SOARCA)
- NRC Level 3 PRA project (in progress)
- Generic Safety Issues Program

This is consistent with the intent of NTTF Recommendation 1.4.

The results of the review of information from the sources listed above could identify new issues that would meet the regulatory definition of the design-extension category. In such cases, NRC would codify the new technical requirement and revise the design-extension category definition to list that new technical requirement as a conforming change as part of the rulemaking for that technical requirement. Every applicant and licensee would be required to treat those regulations (and only those regulations) as encompassing the design bases extension category of events and accidents. As currently envisioned by the staff, no applicant or licensee would be required to conduct a plant-specific analysis to identify the events and accidents that should be regarded as falling within the design-extension category for their plant, and the regulatory requirements that should be regarded as design-extension for purposes of applying the special treatment requirements.

Evaluation of Generic Design Extension Category Events and Accidents

Applicants and current licensees would be required to perform an evaluation to (1) show how acceptance criteria specified in each of the design-extension category regulations are met and (2) identify those design features and programmatic activities (e.g., procedures) relied upon to mitigate design-extension events in order to meet the acceptance criteria. Acceptance criteria could be general, where they would apply to all events in the category or they could be event-specific like those in 10 CFR 50.62, ATWS or 10 CFR 50.63, Station Blackout, since the events in the design-extension category will be specified by the NRC in the regulations. General criteria would be specified in the rule establishing the design-extension category. An example of general criteria applicable to all events could be something similar in concept to the acceptance criteria in 10 CFR 50.150, “Aircraft Impact Assessment”, which are that either the reactor core remains cooled or the containment remains intact[3]. The methods and assumptions for performing the evaluation of design-extension events could either be specified in the regulations or in regulatory guidance referenced in the regulation. The NRC typically specifies methods and assumptions acceptable to the NRC staff for analyses and evaluations in guidance documents. The methods and assumptions for evaluation of design-extension events would likely differ from those used for analyzing design-basis events. Whereas design-basis accidents assume a single failure, loss of offsite power, and additional margins on analysis parameters, the design-extension events rule may relax some or all of these assumptions. For

[3] The terms “reactor core remains cooled” and “containment remains intact” are defined in guidance for performing aircraft impact assessments.

example, "best-estimate" and realistic approaches may be allowed for the analysis of design-extension events.

Treatment Requirements for SSCs Credited for Meeting DEE Acceptance Criteria

The NRC would specify, by regulation, what "regulatory treatment requirements" should apply to design-extension category SSCs. By "regulatory treatment requirements," the staff means those NRC requirements intended to ensure that SSCs will be able to meet the necessary functions to address design-extension events and accidents. The potential list of treatment requirements will likely be a subset of the existing NRC treatment requirements applicable to design-basis events and accidents, *e.g*., 10 CFR Part 50, Appendix A, quality assurance; 10 CFR 50.49, environmental qualification of electrical equipment; and 10 CFR Part 50, Appendix J, containment testing. Table 1 provides an example list of areas for which treatment requirements could be developed. An example of specifying treatment requirements in the regulations is provided in 10 CFR 50.69(b).

This approach to treatment of SSCs is consistent with the staff's understanding of the NTTF's implicit assumption in recommending the regulatory establishment of the "design-extension" category, that the full set of treatment requirements applicable to safety-related SSCs (which address design-basis events and accidents) would not apply to design-extension SSCs. Otherwise, there appears to be little reason to establish a new design-extension category separate from existing design-basis event/accident categories, as the key significance of the design-basis categorization is the application of special treatment requirements.

Table 1.
Potential Elements of Special Treatment

- Design requirements for independence, redundancy, and diversity
- Codes and Standards for design, material procurement, fabrication, construction, and operation
- Seismic design-basis
- Seismic qualification testing
- Equipment qualification testing
- Quality assurance and quality control
- Maintenance Requirements
- Availability Controls
- Materials surveillance testing
- Pre-service and in-service inspection
- Pre-service and in-service testing

Requirements Governing Design Extension

The staff believes that two types of regulatory requirements would need to be adopted to ensure that nuclear power plants implement the design-extension categorization effectively. The first is a positive regulatory requirement that nuclear power plants be designed, constructed and operated in accordance with the design-basis-extension categorization and special treatment designation requirements. This would be included in the regulation establishing the list of design-extension regulations, DEE evaluation requirements and the designated treatment requirements. The second set of conforming regulatory changes would be to § 50.34, governing the content of a PSAR and FSAR, 10 CFR 50.71, governing the updating of the FSAR, and various provisions throughout Part 52 governing the content of applications for design approvals, design certifications, combined licenses, and manufacturing licenses. These regulations would be revised to explicitly require the applicable regulatory document to: (i) specify the design-extension regulations as constituting part of the design bases for the plant; and (ii) describe how the applicant is complying with the design-extension regulations with respect to categorization and treatment, including a list of the SSCs that are considered to be needed to address design-extension requirements. A third set of conforming changes in Part 50 may – at the discretion of the Commission – be adopted for purposes of clarity. These changes, to those regulations which the NRC has designated as falling within the design-extension category, would simply specify their status as design-extension.

Key Issues

The NRC staff will address the following issues:

- On what basis must DEEs be identified, and how should that basis differ, if at all, from the basis for identifying DBAs and BDBAs?

- What acceptance criteria must be met to show that the plant's licensing basis adequately addresses design extension events? For example, must DEEs meet acceptance criteria with specified conservative assumptions (e.g., single failure, loss of offsite power); and, should the criteria be general or event specific?

- How will non-safety related SSCs that are relied upon to mitigate design-extension events be treated?

- Is it feasible to specify a common (or minimum baseline) set of design or operating requirements for DEEs, or must different requirements be specified for each DEE?

- What methods will be used to evaluate DEEs?

- How will the NRC review and approve each plant's licensing basis demonstrating that the design extension events (however they are specified or determined) are adequately addressed? What review guidance is needed?
- Are the criteria for balancing risk, DID and SM the same for DEEs as for DBAs?

Expected Products

To implement this option, the staff will need to develop some or all of the following products:

- Revision to 10 CFR 50.2 to explicitly define DBA and create DEE

- New rule to:
    - establish DEE category
    - identify events in the category
    - specify acceptance criteria for evaluation of DEE
    - describe acceptable evaluation methods or reference regulatory guidance
    - specify general treatment requirements for design features and procedures credited in the evaluation of DEE
    - establish requirements for addressing the impact of changes to the facility on the evaluation DEE

- Revision to 10 CFR 50.34 and comparable changes to Part 52 to require analysis of DBAs and DEEs to be included in the application and to 10 CFR 50.71 to require inclusion in the updated FSAR

- Regulatory guidance for implementation of Design-extension requirements

- Regulatory guidance and Standard Review Plans (SRP) for design features credited only in the evaluation of DEE and not DBA

- SRP section for review of licensee/applicant implementation of design-extension requirements

- NRC Inspection procedures for monitoring implementation of special treatment requirements

Pros and Cons for this Option

<u>Pros</u>:

- The public would have assurance that provisions are in place to mitigate DEEs and are being controlled with a common standard approved by the NRC

- This option would increase the transparency to the public and to licensees of NRC's regulatory requirements for design-basis and beyond design-basis accidents and events

- Possible standardization of treatment requirements for SSCs credited in meeting DEE acceptance criteria could reduce administrative burden and associated costs of maintaining equipment required to prevent or mitigate DEEs

- Establishment of this new category of regulations would be consistent with accepted international practice

<u>Cons</u>:

- Systematic characterization of existing and future events as DEEs could require significant resources to clarify NRC requirements without a commensurate increase in the assurance of adequate protection or level of public health and safety

- The creation of a DEE category may increase regulatory uncertainty for stakeholders and NRC staff during the time required to conduct rulemaking and develop guidance

- Existing NRC policy on the use of PRA by applicants and licensees may need to be revised in light of the minor role played by PRA in the NRC's framework for addressing events outside the current design-basis, including severe accidents

Estimated Resources

Industry implementation costs (108 plants)	$4,864,000
NRC implementation costs	$2,717,000
Total implementation costs	$7,580,000

Option 4b: Establish a Design Basis Enhancement Category for Power Reactor Regulations Using a Plant Specific PRA

Summary of option

This option would establish a design-enhancement category for power reactor regulations that, in concert with DBAs, will be used to ensure adequate protection and additional protection of public health and safety. The NRC would require licensees to have and upgrade plant-specific PRA models of specified scope and level of detail. Licensees would also be required to perform periodic updates of the PRA models and periodic reviews and analyses to identify relevant design-enhancement scenarios and determine appropriate actions. Licensees would also be required to perform effective cost-benefit analyses when considering how to address design-enhancement events. This option would implement a risk-informed and performance-based defense-in-depth regulatory approach.

Background

Refer to background for Option 4a.

Relationship to NTTF Recommendation 1

The NTTF considered the current NRC regulatory framework as one that "… has come to rely on design-basis requirements and a patchwork of beyond-design-basis requirements and voluntary initiatives for maintaining safety." The NTTF observed that "… for new reactor designs, the Commission's expectations that beyond-design-basis and severe accident concerns be addressed and resolved at the design stage are largely expressed in policy statements and staff requirements memoranda, only reaching the level of rulemaking when each design is codified through design certification rulemaking." The NTTF supported a more formal approach that would include "extended design-basis events" in a new regulatory framework:

The Task Force envisions a framework in which the current design-basis requirements (i.e., for anticipated operational occurrences and postulated accidents) would remain largely unchanged and the current beyond-design-basis requirements (e.g., for ATWS and SBO) would be complemented with new requirements to establish a more balanced and effective application of defense-in-depth.

The NTTF report goes on to say:

> This framework, by itself, would not create new requirements nor eliminate any current requirements. It would provide a more coherent structure within the regulations to facilitate Commission decisions relating to what issues should be subject to NRC requirements and what those requirements ought to be. … Such changes would establish a more logical, systematic, and coherent set of requirements addressing defense-in-depth.

Relationship to RMTF report

This option would implement the recommendations of the RMTF report for operating and new power reactors as described in NUREG-2150, Appendix H.2.2. Therefore, it is directly related to the RMTF report.

Detailed Description of Option

This option would, by regulation: (i) add a design-enhancement category of events to be included in the NRC's regulatory framework for nuclear power plants and specify the criteria of such events and accidents that licensees will use to identify design-enhancement events that must be included in a plant's licensing basis, (ii) require applicants and licensees to prepare, maintain and upgrade a plant-specific PRA and to use the risk insights to identify potential design-enhancement events, (iii) establish the "regulatory treatment requirements" applicable to the design-enhancement events; and (iv) require applicants and licensees for nuclear power plants (including applicants for design approvals, design certifications and combined licenses under Part 52) to comply with applicable design-enhancement requirements and to include in applications and FSAR updates (as applicable) information on design-enhancement categorization and compliance. The new requirements would specify analysis methods, assumptions, and acceptance criteria for demonstrating the ability to mitigate these design-enhancement events, as well as minimum treatment requirements for the involved equipment and procedures. The new categorization requirements would be imposed on existing nuclear power plants (including already-approved design certifications and combined licenses, as well as future plants (including applications currently in process).

At this time, the staff believes that the option would be implemented with a number of regulations. A definition of design-enhancement events, risk management, and risk-informed and performance-based defense-in-depth would be set forth in 10 CFR 50.2, *Definitions*. A new regulation (10 CFR 50.x) would be added to introduce the design-enhancement event category and define the thresholds and acceptance criteria for the scenarios. 10 CFR 50.x would likely define common attributes, such as change control, documentation, and reporting. It would also establish the appropriate treatment of equipment and operating controls. Existing requirements, such as SBO, ATWS, and AIA, could be re-designated as design-enhancement events. A requirement (10 CFR 50.y) would be included for licensees to periodically assess and address potential events meeting thresholds derived from the risk-informed and performance-based defense in depth definition. The technical analyses would involve risk assessments (e.g., PRAs) and other techniques, as necessary, to address relevant scenarios. A new regulatory requirement requiring the preparation, maintenance and upgrading of a PRA meeting NRC-specified quality requirements (this may involve changes to 10 CFR 50.71(h), or the development of a completely new rule, 10 CFR 50.z). Conforming changes to 10 CFR 50.34 and analogous provisions in Part 52 requiring various nuclear power plant applications to include information on compliance with the various design-enhancement requirements.

Design-Enhancement Category Description

This option would require each NPP licensee to identify design-enhancement events for its plant based upon the NRC-established criteria/description of accidents that must be included in a plant's licensing basis. These criteria will utilize both deterministic and plant-specific risk information. The plant-specific risk information would be developed in accordance with an NRC required, plant-specific PRA meeting NRC's quality and method requirements for such PRAs. The staff would use Alternative 2 of Appendix H to NUREG-2150 in developing the regulations necessary to implement this option.

The RMTF recommendation parallels and even subsumes NTTF Recommendation 1 to a large extent. The accident at the Fukushima Dai-ichi nuclear power plants in Japan occurred shortly after the RMTF was established. The RMTF's analysis was influenced by the events at

Fukushima and the subsequent studies, including the NRC Near-Term Task Force, and the continuing discussions on the accident's implications for U.S. nuclear power plants. For this reason, the RMTF framework as applied to operating and new reactors addresses the major concerns identified by the NTTF regarding the NRC's regulatory framework.

This option differs from Option 4a in several important respects. First, this option would specify criteria for licensees to use in determining which events should be included in the design-enhancement category. In Option 4a, the NRC would specify the design extension events to be analyzed. Second, this option requires plant-specific PRA analyses. Option 4a would use generic risk information and other sources; there would be no PRA requirement. Finally, this option "enhances" the design basis events/accidents to add "additional protection" that improves safety beyond the level required for reasonable assurance of adequate protection. Option 4a "extends" the design basis events/accidents with events that must be analyzed in order that adequate protection is reasonably assured.

Plant-Specific PRA Requirement

NRC would require, by rule, that each nuclear power plant develop and maintain a plant-specific PRA. This rule would be similar to the requirement for new reactors in 10 CFR 50.71(h), and a new or revised regulation would require licensees to perform periodic reviews and analyses to identify relevant scenarios and determine appropriate actions to address design-enhancement events. Option 4b would be implemented using Level 1 and 2 PRA models that estimate CDF and LERF. A requirement similar to 10 CFR 50.71(h) would have licensees upgrade their PRAs to cover initiating events and modes contained in NRC-endorsed consensus standards on PRA in effect one year prior to each required upgrade. 10 CFR 50.71 (h) requires upgrades every four years. The technical analyses would involve risk assessments (e.g., PRAs) and other techniques, as necessary, to address relevant scenarios. The NRC staff agrees with the RMTF that this approach could address matters such as GSI-199, "Implications of Updated Probabilistic Seismic Hazard Estimates in Central and Eastern United States on Existing Plants," and the periodic assessments recommended in the Fukushima NTTF report.

Licensee Designation of Plant-Specific Design-Enhancement Category Events and Accidents

As stated above, each licensee would be required to determine the set of design-enhancement events using its plant-specific PRA, deterministic information, and criteria set forth in NRC regulations. The NRC would define the threshold for events falling within the design-enhancement category to ensure that the risks resulting from the failure of established barriers and controls are maintained acceptably low. The threshold would, as much as possible, build upon existing practices, such as the requirements and guidance for regulatory analyses, backfits, severe accident mitigation alternatives (SAMAs), and risk-informed licensing (e.g., Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-informed Decisions on Plant-specific Changes to the Licensing-basis." The NRC staff could also consider the criteria developed under Option 3 of this paper for determining whether adequate defense-in-depth and safety margins have been addressed in the design and operation of a nuclear power plant. NRC could specify additional design-enhancement events based upon the need for a plant to demonstrate an acceptable balance among risk, DID and safety margins.

The Risk Management Task Force (RMTF) in Section H.2.2, "Alternative 2: NRC Identifies Thresholds for Event Sequences, Acceptance Criteria Are Based on ALARA Principles," of Appendix H to NUREG-2150 found that there are many considerations in the identification of appropriate thresholds, including the analysis techniques (e.g., scope and level of PRAs), the handling of uncertainties, and the definition of relevant scenarios. One element of the thresholds could, for example, be defined in terms of relevant scenarios (defined by a single or group of PRA sequences) with an estimated core damage frequency (CDF) greater than 10^{-5} per year or a large early release frequency (LERF) greater than 10^{-6} per year. At the point when Level 3 PRAs become available, the NRC's Quantitative Health Objectives (QHO) or other societal measures could be directly considered as part of the event categorization criteria. Other criteria or relevant scenarios could be included, as needed, to complement the frequency-related parameters (e.g., security events, aircraft impact for new reactors). The RMTF also found it necessary to define approaches for addressing initiating events (e.g., seismic) for which either the conditional failure probability or the uncertainties increase dramatically as frequencies are reduced to levels approaching the thresholds for inclusion or the acceptance criteria defined for the design-enhancement category (e.g., 10^{-5} per year).

NRC staff anticipates establishing thresholds for scenarios with an estimated CDF greater than 10-5 and LERF greater than 10-6, which is generally consistent with the NRC's guidelines for performing regulatory analyses. The NRC staff does not recommend that the Commission consider other societal risk measures at this time. The staff is currently investigating possible impacts of Level 3 PRAs on the NRC's regulatory framework as part of its efforts associated with SECY 12-0123,"Update on Staff Plans to Apply the Full-Scope Site Level 3 PRA Project Results to the NRC'S Regulatory Framework." As stated in SECY 12-0123, results from the Level 3 PRA project can be used to enhance the technical basis for using risk information, improve the PRA state-of-practice, and identify safety and regulatory improvements.

The RMTF described the acceptance criteria for the periodic analysis performed by licensees for design-enhancement events in terms of the "as low as is reasonably achievable" or ALARA principle, similar to that used in the radiation protection arena. The process would employ the decisionmaking process described in Chapter 2 of NUREG-2150. The staff would use much of the existing guidance (updated, as needed) for regulatory analyses, backfits, SAMAs, and risk-informed licensing actions. The RMTF felt that this should help provide consistency between evaluations performed by licensees and the NRC staff. The RMTF stated that existing guidance includes several criteria, one of which is a factor of dollars per person-rem (roentgen equivalent man) avoided through the installation of additional design features to address severe accident scenarios. The development of this alternative would include defining, as appropriate, periodicity for the analyses to identify and address the new design-enhancement events. The staff anticipates that this would be on the order of every 4 years or when new information presents itself.

The staff notes that the changes to the Backfit Rule may be required, in order to reflect the dynamic nature of a plant's licensing basis. The underlying policy basis for "backfitting" protection may not be relevant where the regulatory requirements and the plant's licensing basis are dynamically being changed by the licensee on an ongoing basis based upon the PRA. Moreover, even if there is some aspect of backfitting protection to be provided, the "baseline" for determining whether backfitting has occurred must be reconsidered in light of the dynamic nature of the licensee-determined regulatory requirements.

Treatment Requirements for SSCs Credited for Meeting Design-Enhancement Acceptance Criteria

The NRC staff expects that special treatment requirements to support the design-enhancement category would be similar to those applied to Risk-Informed Safety Class-2, meaning nonsafety-related structures, systems and components that perform safety significant functions as defined in 10 CFR 50.69, "Risk-informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors," and the regulatory treatment of non-safety systems (RTNSS) for new reactors.

For full details on this option, the reader is encouraged to refer to Appendix H.2.2 of NUREG-2150.

Key Issues

As with Option 4a, the overarching technical and policy issue is whether the design-enhancement category should be regarded as an adequate protection requirement, or whether it represents an "enhanced" level of safety beyond that needed for adequate protection. Option 4b would represent an "enhanced" level of safety beyond that needed for adequate protection.

There are a number of policy issues associated with this option, some of which represent significant changes to existing policies, including additions to and reversals of past practices. These policy issues and other key issues are:

- NRC would explicitly define a category of events that rely on the "additional protection" provision of the AEA, called the design enhancement category. Currently, the backfit rule would require an analysis of each proposed backfit. The new category would create a new class of events that could be exempted from the regulatory analysis portion of the backfit rule.
- The burden for demonstrating whether measures to implement an "additional protection" feature would be on licensees. Current policy is that NRC staff must demonstrate that a substantial safety improvement is justified in terms of cost.
- NRC would implement a risk-informed and performance-based approach to determining when DID is adequate. Currently, DID is seen as deterministic and somewhat independent of risk.
- The NRC may need to change its safety goals to reflect the ALARA concept for risk to the public. The current safety goal policy defines "how safe is safe enough."
- The NRC would require licensees of operating reactors to perform and periodically upgrade PRAs. Currently, only new reactors have such a requirement.
- The NRC needs to decide whether the design-enhancement category would be implemented on a generic or plant-specific basis. Generic implementation means the set of DBAs and design-enhancement events would be specified for classes of plants (e.g., BWR, PWR). Plant-specific implementation would mean that each plant's list of events would be unique. If a generic design-enhancement category was implemented based on results of plant-specific PRAs, the approach would be a hybrid implementation of aspects of both Options 4a and 4b.
- Licensees or Applicants would perform periodic reviews and analyses to identify relevant scenarios and determine appropriate actions to address design-enhancement events. Currently, the design enhancement category does not exist, so there is no such requirement.

Expected Products

This Option would result in the following:

- The NRC would issue a rule to require licensees to identify and address design-enhancement events. The rule would define the design-enhancement event category, define the thresholds and acceptance criteria for the scenarios, and likely define common attributes for the category, including change control, documentation requirements, reporting requirements, and treatment requirements for equipment and operating controls used to mitigate design-enhancement events. Existing requirements, such as SBO, ATWS, and AIA, could be superseded by, incorporated (with either existing or revised requirements), or referenced in the new regulation.
- A requirement would be included for licensees to periodically assess and address potential events meeting thresholds derived from the risk-informed and performance-based defense in depth definition. The technical analyses would involve risk assessments (e.g., PRAs) and other techniques, as necessary, to address relevant scenarios.
- A new regulatory requirement requiring the preparation, maintenance and upgrading of a PRA meeting NRC-specified quality requirements (this may involve changes to 10 CFR 50.71(h), or the development of a completely new rule, 10 CFR 50.z).
- Conforming changes to 10 CFR 50.34 and analogous provisions in Part 52 requiring various nuclear power plant applications to include information on compliance with the various design enhancement requirements.
- NRC would update guidance documents consistent with the new policy statement and the rules. Example guidance that would be updated includes the backfit guidelines, the CRGR Charter, the Regulatory Analysis guidelines, the Significance Determination Process, and the Generic Issues Program, to list a few.

Dependencies Among Options

Option 4b as described in Alternative 2 of Appendix H to NUREG-2150 would also require implementing Option 3 for establishing decision criteria for balancing risk, defense-in-depth, and safety margins because it would include adding definitions for risk management and risk-informed and performance-based defense-in-depth, and, thereby, effectively include Option 3.

Pros and Cons for this Recommendation

The WG identified the following considerations that favor this recommendation (pros) and others that are not favorable (cons).

<u>Pros</u>

Implementation of Option 4b would address the following:

- NTTF Recommendations 1.1 and 1.2, in that the RMTF framework includes risk-informed DID, considers both adequate protection and additional protection, and includes an enhanced design basis accident category similar to the NTTF extended design basis category.

- NTTF Recommendation 1.3, in that the regulatory analysis guidelines would be one of many guidance documents that would require updating to implement this option.
- The intent of NTTF Recommendation 1.4, in that the plant-specific PRA requirement would identify potential generic regulations or plant-specific regulatory requirements using more current information that the reports referenced by the NTTF.
- NTTF Recommendation 2.2, in that the periodic update of the plant-specific PRA models and "living" requirement to maintain the design-enhancement category of events would account for new information on seismic and flooding hazards.
- The requirement of Section 402 of the December 23, 2011, Consolidated Appropriations Act, Public Law 112-074, in that the periodic update would include all external hazards.
- NTTF Recommendation 3, in that the plant-specific PRA models would be expected to meet consensus standards as endorsed by NRC, and the issue of seismically induced fires and floods is certain to be addressed by those standards in the future.
- This option would improve the efficiency and efficacy of the NRC's handling of new information, including but not limited to new information on external hazards.
- The requirement for plant-specific PRAs will provide additional benefits beyond the scope of this option. Inspection and enforcement of the maintenance rule would be improved. The SDP part of the ROP would be more efficient. Evaluation of potential generic safety issues would be improved. The use of risk insights in licensing activities could be greatly expanded. Licensees could adopt risk managed Technical Specifications, which would reduce emergency TS changes and NOEDs, resulting in greater regulatory efficiency.
- Implementation of this recommendation would provide additional assurance that nuclear power plants can cope with challenges that were not considered in the initial design and licensing. This includes challenges that have not yet been thought of, or for which analysis is problematic (e.g., terrorist activities).

<u>Cons</u>

- If the plant-specific approach is used to identifying events in the design basis and design-enhancement category, NRC would have to review and approve each licensee's selection of extended or enhanced events. Otherwise, a licensee could be in violation any time a new insight or scenario was identified that would meet the criteria for this type of event, resulting in regulatory unpredictability.
- NRC inspectors and reviewers must be familiar with a plant's PRA in evaluating safety issues, and plant-specific information.
- Since plant-specific PRA models will be required, processes will be needed to address the changing risk profile when models are updated or upgraded. For example, updated techniques or data could significantly change the risk profile of a plant that could indicate a different list of events. This would result in regulatory unprectability.
- The existing process, of writing issue-specific rules to address beyond design basis events as they are identified, has worked well and is less resource intensive than this proposed change. It allows for involvement of the public, industry, and other interested parties on the specific issue, not on a set of plant-specific criteria that may or may not result in any additional events.

- The current combination of prescribed DBAs and selected beyond DBA rules has worked well. Additional requirements have been imposed as a result of the Fukushima event. Risk assessments have been performed for all US nuclear power plants. There is likely little safety benefit to be gained in creating this category.
- If numerically-based decision criteria are established based upon PRA, such criteria may reduce the discretion of the NRC decisionmaker in addressing any given issue or circumstance. If the Commission wishes to rely on favorable PRAs in one instance to show that the numerical guidelines have been met, it must be prepared to abide by unfavorable PRAs in another, or face the charge, seemingly difficult to refute, that it is being arbitrary and capricious in its handling of these numerical analyses. [OGC has previously advised the Commission on this subject].
- Unless this Option is combined with Option 3, then the NRC must address the potential for diminishing or ending its reliance on the deterministically-informed concepts of single failure, defense in depth (including required mitigative measures), redundancy and diversity. The criteria for assessing generic rulemaking, including that in the Backfit Rule, 10 CFR 50.109, and the standards in the Commission's Regulatory Analysis Guidelines, NUREG/BR-0058, would have to be substantially modified to reflect the move to a risk-informed paradigm of adequate protection. A comprehensive, integrated review of the Commission's regulations would need to be performed in order to assure that conforming changes are made to accommodate a move to risk-informed regulation. Such a change in regulatory approach would have to be justified and explained in the statement of considerations accompanying any rulemaking and regulatory guidance implementing the change. [OGC has previously advised the Commission on this subject].
- In any initial licensing proceeding and initial design certification rulemaking, the adequacy of the entire PRA and its inputs would be subject to challenge (for licensing, this would be in an adjudicatory hearing). In any license amendment and design certification rule amendment proceeding, it is unclear whether there would be a defensible basis for limiting the scope of a potential challenge to the adequacy of the PRA. Significant NRC resources may be expended in an adjudicatory proceeding where PRA adequacy is challenged. [OGC has previously advised the Commission on this subject].

Estimated Resources (in 2012 dollars; 3% and 7% discount rates)

Industry implementation costs (104 plants)	$78,358,000 (7%) $100,358,000 (3%)
NRC implementation costs	$5,071,000
Total implementation costs	$83,400,000 (7%) $105,000,000 (3%)

Appendix – Estimated Implementation Costs

These resource estimates are very preliminary, do not include any potential offsets (savings or gains in efficiencies), and are subject to change.

Option 1 - Maintain the existing regulatory framework (status quo)

There are no NRC or licensee costs or resource impacts associated with this option.

Option 2 - Clarify role of voluntary industry initiatives in NRC regulatory process

Option 2 – Estimated Savings and Cost Burdens				
	Hours per action	No. of actions	Labor rate	Implementation Cost
Industry Costs				
Prepare generic industry procedure template to conform with policy statement	3120	1	$105	$327,600
Licensees adopt template for facility use	80	104	$105	$873,600
Subtotal				$1,201,000*
NRC Costs				
Prepare a Policy statement regarding voluntary initiatives for public comment	1000	1	$119	$199,000
Resolve public comments and publish the final Policy statement	674	1	$119	$80,206
Revise existing NRC guidance documents to conform with policy statement	80	19	$119	$180,880
Subtotal				$460,000*
			Total	$1,661,000*
			Average industry cost per unit	$12,000*

Optional – Rulemaking & plant verification, if required

Following the publication of the policy statement the NRC could perform a retrospective review of existing industry initiatives and make a finding that regulatory action is required where a question of adequate protection exists. This cost estimate estimates the cost burden for the NRC to perform the associated rulemaking and licensee costs to verify compliance with the new regulation.

	Hours per action	No. of actions	Labor rate	Implementation Cost
Industry Costs				
Facility inspection and review of design documentation	160	104	$105	$1,747,200
Document verification results	80	104	$105	$873,600
Subtotal				$2,621,000*

	Hours per action	No. of actions	Labor rate	Implementation Cost
NRC Costs (if required) Rulemaking establishing requirements for previously voluntary initiative(s)	3348	1	$119	$398,000*
Subtotal				$398,000*
			Total	$3,019,000

*Numbers rounded to the nearest thousand dollars

NRC staff believes that expected qualitative values resulting from the Option 2 will contribute substantially to the benefits of NRC's regulatory framework, in particular with regard to accountability and control of devices and the sources that they contain. These qualitative values include:

- *Enhanced NRC Ability to Protect Public Health and Safety.* Requiring nuclear power plant and fuel facility licensees to implement those voluntary initiatives for which legally requirements should be imposed would ensure that the safety benefits derived from voluntary licensee initiatives would be consistently maintained over time. Consequently, this option will enhance NRC ability to protect public health and safety.
- *Improved Regulatory Efficiency.* Resolves issues where voluntary industry initiatives were treated in a less rigorous and formal manner so much so that the program would have resulted in multiple violations had it been associated with a required regulatory program. Providing a greater reliance on regulatory processes ensures full and continued implementation and can improve overall regulatory efficiency by increasing accountability among all of the parties.
- *Increased Public Confidence.* Requiring nuclear power plant and fuel facility licensees to implement those voluntary initiatives for which legally requirements should be imposed would be subject to NRC inspection and enforcement programs. This would ensure that the safety benefits derived from voluntary licensee initiatives would be consistently maintained over time to comply with regulations. This will result in increased public confidence in regulation and addresses the public's misconception that the NRC was encouraging the use of voluntary commitments at the expense of regulatory action.

Option 3 – Establish process and considerations for balancing risk, defense-in-depth and safety margins

This option would establish the Commission's expectations with regard to risk-informed regulatory decision process for balancing risk, defense-in-depth, and safety margins. It would establish Commission expectations or requirements for licensees to have and maintain risk assessments of a specified scope, level of detail, and technical adequacy. It would define the objective of defense-in-depth and the principle elements of defense-in-depth. This option would also explicitly define the objective and principles related to safety margins. It would establish a risk-informed, regulatory decision process for balancing risk, DID and safety margins. This would include the NRC developing criteria for determining whether adequate defense-in-depth and safety margins have been addressed in the design and operation of a nuclear power plant.

Option 3 – Estimated Burden – One-Time Implementation Costs				
	Hours per action	No. of actions	Labor rate	Implementation Cost
Industry Costs				
Prepare generic industry procedure template to conform with NRC guidance document	3120	1	$105	$327,600
Licensees adopt template for facility use	80	108	$105	$907,200
Subtotal				$1,235,000*
NRC Costs				
Prepare a Policy statement regarding risk-informed regulatory decision making for public comment	1000	1	$119	$119,000
Resolve public comments and publish final policy statement	674	1	$119	$80,206
Rulemaking establishing requirements for having and maintaining plant-specific PRA models	3348	1	$119	$398,000
Prepare a new MD for risk-informed decision making NRC guidance documents to conform with policy statement	500	1	$119	$59,500
Prepare and issue new guidance that provides criteria and methodology for using a blend of deterministic and probabilistic processes on a plant-specific basis.	2400	1	$119	$285,600
Revise existing NRC guidance documents to conform with policy statement	160	5	$119	$95,200
Subtotal				$1,038,000*
			Total	$2,273,000*
			Average industry cost per unit	$21,000*

*Numbers rounded to the nearest thousand dollars

Optional tasks, if required

The policy statement and MD would provide the criteria for how defense-in-depth should be implemented. However, determining if an individual licensee has adequate defense-in-depth is determined on a plant-specific basis. The most efficient approach would be to use a plant-specific PRA. Moreover, one level of defense would involve emergency planning and the potential acceptance guidelines could involve consequences. Below is the estimated burden for those plants which do not have a plant-specific PRA.

	Hours per action	No. of actions	Labor rate	Implementation Cost
Industry Costs (if required)				
Upgrade plant-specific PRA	3120	68	$105	$22,276,800
Peer review plant specific PRAs	624	68	$105	$4,455,360
			Total	$26,732,000*
			Average industry cost per unit	$393,000*

*Numbers rounded to the nearest thousand dollars

Assumptions

1. New plants and existing plants with plant-specific PRAs have negligible work to upgrade their PRA to meet these new requirements. (There are 36 of 104 existing units that have or have committed to have fire PRAs.)

Option 4a - Establish design-basis enhancement on a generic basis

(i) add a design enhancement category to NRC's regulatory framework for nuclear power plants and specify the attributes of such events and accidents;
(ii) identify the set of NRC technical regulations that address design enhancement events and accidents;
(iii) establish the regulatory treatment requirements applicable to the NRC-designated set of design enhancement regulations; and
(iv) require applicants and licensees for nuclear power plants (including applicants for design approvals and design certifications under Part 52) to comply with applicable design enhancement requirements for categorization and the minimum treatment requirements specified in the regulations, and to include in applications and FSAR updates (as applicable) information on design enhancement categorization and compliance.

The new categorization requirements would be imposed on existing nuclear power plants (including already-approved design certifications and combined licenses, as well as future plants (including applications currently in process).

The specific changes performed by rulemaking are listed below:

- § 50.2 – Add a new definition for *design enhancement* category to supplement the current definitions for *design basis event* and *design basis accident.*
- Add a new § 50.1XX – This new section would required nuclear power plants to be designed, constructed, and operated to address design enhancement events and accidents, as defined in § 50.2.
- § 50.34 – Conforming changes requiring each applicant for a nuclear power plant construction permit or nuclear power plant operating license under part 50 or each applicant for a design certification, design approval, combined license, or manufacturing license under part 52 shall include information on compliance with various design enhancement requirements under the new § 50.1XX.
- § 50.69 – Conforming changes to existing risk-informed categorization and treatment of structures, systems and components for nuclear power reactors.

Implementation details would be contained in a new guidance document that accompanies the rulemaking. In preparing this guidance document, the staff would recommend those plant events and accidents that would be categorized as design enhancement events and accidents.

Option 4a Estimated Burden – One-time Implementation Costs				
	Hours per action	No. of actions	Labor rate	Implementation Cost
Industry Costs	-	-	-	-
Prepare generic industry procedure template to conform with NRC guidance document	3120	1	$105	$327,600
Licensees adopt template for facility use	80	108	$105	$907,200
Licensees prepare submittal and resolve NRC comments	320	108	$105	$3,628,800
Subtotal				$4,864,000*
NRC Costs				
Rulemaking establishing design basis enhancement requirements on a generic basis	3348	1	$119	$398,412
Prepare new guidance document	2200	1	$119	$261,800
Review submittals and prepare and issue SERs	160	108	$119	$2,056,320
Subtotal				$2,717,000*
Total				$7,580,000*
Average Industry cost per unit				$45,000*

Option 4b - Establish a design basis enhancement category for power reactor regulations using a plant specific PRA -

This option would establish a design-enhancement category for power reactor regulations that, in concert with DBAs, will be used to ensure adequate protection and additional protection of public health and safety. The NRC would require licensees to have and upgrade plant-specific PRA models of specified scope and level of detail. Licensees would also be required to perform periodic updates of the PRA models and periodic reviews and analyses to identify relevant design enhancement scenarios and determine appropriate actions. Licensees would also be required to perform effective cost-benefit analyses when considering how to address design-enhancement events. This option would implement a risk-informed and performance-based defense-in-depth regulatory approach.

This option would, by regulation:

(i) add a design enhancement category of events to be included in the NRC's regulatory framework for nuclear power plants and specify the criteria of such events and accidents that licensees will use to identify design-enhancement events that must be included in a plant's licensing basis,

(ii) require licensees to maintain and upgrade a plant-specific PRA and to use the risk insights to identify potential design-enhancement events,

(iii) establish the "regulatory treatment requirements" applicable to the design enhancement events; and

(iv) require applicants and licensees for nuclear power plants (including applicants for design approvals, design certifications and combined licenses under Part 52) to comply with applicable design enhancement requirements and to include in applications and FSAR updates (as applicable) information on design enhancement categorization and compliance.

The new requirements would specify analysis methods, assumptions, and acceptance criteria for demonstrating the ability to mitigate these design enhancement events, as well as minimum treatment requirements for the involved equipment and procedures. The new categorization requirements would be imposed on existing nuclear power plants (including already-approved design certifications and combined licenses, as well as future plants (including applications currently in process).

The specific changes performed by rulemaking are listed below:

(i) Add definitions of design-enhancement events, risk management, and risk-informed and performance-based defense-in-depth under 10 CFR 50.2, *Definitions*.

(ii) Add a new regulation (10 CFR 50.1XX) to establish the design-enhancement event category, define the thresholds and acceptance criteria for the scenarios, and the appropriate treatment of equipment and operating controls.

(iii) Rescind any existing requirements (e.g., station blackout, anticipated transients without SCRAM, and aircraft impact accident) that meet the criteria for design enhancement events.

(iv) Modify 10 CFR 50.71(h) to include operating reactors and to add any additional PRA requirements necessary to support identification of design enhancement events.

(v) Conform 10 CFR 50.34 and analogous provisions in Part 52 requiring various nuclear power plant applications to include information on compliance with the various design enhancement requirements.

Key assumptions

- maintenance of the PRA until permanent cessation of operations;
- upgrading of the PRA every 4 years to cover initiating events and operational modes contained in NRC-endorsed consensus standards in effect 1 year prior to each required upgrade; and
- one-time upgrading of the PRA to cover all modes and all initiating events for those operating plants that don't have a plant specific PRA (e.g., 68 of 104 units)
- The requirement for a plant specific level 2 PRA does not impose additional burden on COLs because COL applicants are required under Section 50.71(h) to prepare a plant-specific PRA and describe the PRA and its results in its COL application and to have a plant-specific PRA covering all modes and all initiating events by the time of fuel load. Estimate uses similar methodology described in Regulatory Analysis – 10 CFR Part 52, "Licenses, Certifications, And Approvals For Nuclear Power Plants," ML071490350]

Implementation details would be contained in a new guidance document that accompanies the rulemaking. In preparing this guidance document, the staff would recommend those plant events and accidents that would be categorized as design enhancement events and accidents.

	Hours per action	No. of actions	Labor rate	Implementation Cost
Industry Costs	-	-	-	-
Prepare generic industry procedure template to conform with NRC guidance document to classify events and accidents	3120	1	$105	$327,600
Licensees adopt template for facility use	80	108	$105	$907,200
Licensees perform plant-specific assessments	500	108	$105	$5,670,000
Licensees prepare submittal and resolve NRC comments	240	108	$105	$2,721,600
Subtotal				$9,626,000*
NRC Costs				
Rulemaking establishing design basis enhancement requirements on a generic basis	3348	1	$119	$398,412
Prepare new guidance document	1465	1	$119	$174,335
Review submittal and prepare and issue SER	740	108	$119	$4,498,200
Subtotal				$5,071,000*
			Total	$14,697,000*
			Average Industry cost per unit	$89,000*

PRA Upgrade to All Mode, All Initiating Events PRA

One-time cost to upgrade PRA to cover all modes and all initiating events.

	Hours per action	No. of actions	Labor rate	Implementation Cost
Industry Costs				
Upgrade plant-specific PRA	3120	68	$105	$22,276,800
Peer review plant specific PRAs	624	68	$105	$4,455,360
			Total	$26,732,000*
			Average industry cost per unit	$393,000*

*Numbers rounded to the nearest thousand dollars

PRA Maintenance

Industry annual PRA maintenance per unit to incorporate new information could be fairly straight-forward, and has been modeled over a range to represent a low estimate, best estimate, and high estimate per year for existing operating reactors PRAs as shown below:

Estimate Type	Hours per year	Labor rate	Annual PRA Maintenance Cost	No. of PRAs	Annual Industry PRA Maintenance Cost
Low	40	$105	$4,200	104	$436,800
Best	200	$105	$21,000	104	$2,184,000
High	600	$105	$63,000	104	$6,552,000

Level 2 PRA requirements maintenance requirements are already established for COLs, therefore, there are no incremental costs for new reactors. For the 104 existing operating units over an estimated 27-year operating life the total estimated burden is:

Licensee type	PRA Maintenance Estimated Burden (2012 dollars)					
	3% Discount Rate			7% Discount Rate		
	Low Est.	Best Est.	High Est.	Low Est.	Best Est.	High Est.
Operating Plant Total	$8,300,000	$42,000,000	$120,000,000	$5,600,000	$28,000,000	$85,000,000
COL Plants Total	--	--	--	--	--	--
Totals	$8,300,000	$42,000,000	$120,000,000	$5,600,000	$28,000,000	$85,000,000

Note: Level 2 PRA requirements already established for COLs – no additional cost.

PRA Upgrades Every 4 Years

Industry periodic PRA upgrades per unit to incorporate new standards or methodologies could be fairly straight-forward to complex. To model this variation, estimates were developed for a low estimate, best estimate, and high estimate as shown below:

Estimate Type	Hours per update	Labor rate	Maintenance cost per PRA update	No. of PRAs	Industry Periodic PRA Update Cost
Low	200	$105	$21,000	104	$2,184,000
Best	480	$105	$50,400	104	$5,241,000
High	1000	$105	$105,000	104	$10,920,000

Level 2 PRA requirements maintenance requirements are already established for COLs, therefore, there are no incremental costs for new reactors. For the 104 existing operating units over an estimated 27-year operating life the total estimated burden is:

Licensee type	PRA Periodic Upgrades Estimated Burden (2012 dollars)					
	3% Discount Rate			7% Discount Rate		
	Low Est.	Best Est.	High Est.	Low Est.	Best Est.	High Est.
Operating Plant Total	$9,200,000	$22,000,000	$46,000,000	$6,100,000	$14,000,000	$30,000,000
COL Plants Total	--	--	--	--	--	--
Totals	$9,200,000	$22,000,000	$46,000,000	$6,100,000	$14,000,000	$30,000,000

<u>Totals</u>

	Option 4b Estimated Burden (2012 dollars)					
	3% Discount Rate			7% Discount Rate		
	Low Est.	Best Est.	High Est.	Low Est.	Best Est.	High Est.
Total Industry	$53,858,000	$100,358,000	$202,358,000	$48,058,000	$78,358,000	$151,358,000
Total NRC	$5,071,000	$5,071,000	$5,071,000	$5,071,000	$5,071,000	$5,071,000
Total	$58,900,000	$105,000,000	$207,000,000	$53,100,000	$83,400,000	$156,000,000